

# **EXHIBIT A**

IN THE UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

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No. 21-2426

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MAGELLAN TECHNOLOGY, INC.,

*Petitioner,*

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

*Respondent.*

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On Petition for Review of a Final Marketing Denial Order  
by the United States Food and Drug Administration

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**DEFERRED JOINT APPENDIX - VOLUME I OF II**  
**(Pages JA 1-266)**

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U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

September 08, 2021

**DENIAL**

Magellan Technology Inc.  
Attention: Dr. Angelico  
820 Southlake Boulevard  
North Chesterfield, VA 23236

**FDA Submission Tracking Number (STN):** PM0001594, see Appendix A

Dear Dr. Angelico:

We are denying a marketing granted order for the products identified in Appendix A.

**Based on our review of your PMTAs<sup>1</sup>, we determined that the new products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that the marketing of these products is appropriate for the protection of the public health (APPH). Therefore, you cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.**

If you choose to submit new applications for these products, you must fulfill all requirements set forth in section 910(b)(1). You may provide information to fulfill some of these requirements by including an authorization for FDA to cross-reference a Tobacco Product Master File.<sup>2</sup> You may not cross-reference information submitted in the PMTAs subject to this Denial.

Based on review of your PMTAs, we identified the following key basis for our determination:

1. All of your PMTAs lack sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth. In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers. This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS.

Alternatively, FDA would consider other evidence but only if it reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time. Although your PMTAs contained a cross-

<sup>1</sup> Premarket Tobacco Product Application (PMTA) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

<sup>2</sup> See guidelines at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files>

sectional survey from a probability-based sample examining demographics and usage of current and former smokers including product-specific (i.e., Juno) items, a focus group of perceptions and intentions, a diary study of users of the products focused on usage and attitudes, and a human factors study, this evidence is not sufficient to support the benefit to adult smokers of using these flavored ENDS because it does not evaluate product switching or cigarette reduction resulting from use of these products over time nor evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors evaluate product switching or cigarette reduction based on flavor type to enable comparisons between tobacco and other flavors. Accordingly, this is insufficient to evaluate the magnitude of the potential benefit to adult users that is needed to complete our assessment.

Without this information, FDA concludes that your applications are insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth and, therefore, cannot find that permitting the marketing of your new tobacco products would be appropriate for the protection of the public health.

We cannot find that the marketing of your new tobacco products is APPH. The review concluded that key evidence demonstrating APPH is absent. Therefore, scientific review did not proceed to assess other aspects of these applications. FDA finds that it is not practicable to identify at this time an exhaustive list of all possible deficiencies.

Your PMTAs lack sufficient information to support a finding of APPH; therefore, we are issuing a marketing denial order. Upon issuance of this order, your products are misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal<sup>3,4</sup> using eSubmitter.<sup>5</sup> Alternatively, submissions may be mailed to:

Food and Drug Administration  
Center for Tobacco Products  
Document Control Center (DCC)  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date<sup>6</sup>; if the due date falls on a weekend or holiday, the delivery

<sup>3</sup> For more information about CTP Portal, see

<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

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PM0001594, see Appendix A

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must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Kenna Randall, Regulatory Health Project Manager, at (301) 796-4164 or Kenna.Randall@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S  
Date: 2021.09.08 14:48:16 -04'00'

Matthew R. Holman, Ph.D.  
Director  
Office of Science  
Center for Tobacco Products

Enclosure **(if provided electronically, the Appendix is not included in physical mail):**

Appendix A – New Tobacco Products Subject of This Letter

STN	PD Number	Product Name	Category	Subcategory	Package Type	Package Quantity	Characterizing Flavor	Additional Property
PM0001594	PD12	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 48mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD20	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 48mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD16	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 48mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD14	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 18mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD10	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 18mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD13	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 0mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD9	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 0mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD19	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 36mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD15	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 36mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD18	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 18mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD17	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 0mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD11	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 36mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device



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sectional survey from a probability-based sample examining demographics and usage of current and former smokers including product-specific (i.e., Juno) items, a focus group of perceptions and intentions, a diary study of users of the products focused on usage and attitudes, and a human factors study, this evidence is not sufficient to support the benefit to adult smokers of using these flavored ENDS because it does not evaluate product switching or cigarette reduction resulting from use of these products over time nor evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors evaluate product switching or cigarette reduction based on flavor type to enable comparisons between tobacco and other flavors. Accordingly, this is insufficient to evaluate the magnitude of the potential benefit to adult users that is needed to complete our assessment.

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If you have any questions, please contact Kenna Randall, Regulatory Health Project Manager, at (301) 796-4164 or Kenna.Randall@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S  
Date: 2021.09.08 14:48:16 -04'00'

Matthew R. Holman, Ph.D.  
Director  
Office of Science  
Center for Tobacco Products

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PM0001594	PD16	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 48mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD14	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 48mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD10	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 18mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD13	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 0mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD9	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 0mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD19	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 36mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD15	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 36mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD18	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 18mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD17	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 0mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD11	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 36mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device

# **EXHIBIT B**

**WARNING LETTER**

**TheSY, LLC d/b/a Element Vape**

**MARCS-CMS 653609 – MAY 31, 2023**

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**Delivery Method:**

VIA UPS and Electronic Mail

**Product:**

Tobacco

---

**Recipient:**

Kenny Sy, Christopher Sy and Vinh Sy

TheSY, LLC d/b/a Element Vape

10620 Hickson St

El Monte, CA 91731-1947

United States

✉ [customerservice@elementvape.com](mailto:customerservice@elementvape.com) (<mailto:customerservice@elementvape.com>)

✉ [returns@elementvape.com](mailto:returns@elementvape.com) (<mailto:returns@elementvape.com>)

✉ [accessibility@elementvape.com](mailto:accessibility@elementvape.com) (<mailto:accessibility@elementvape.com>)

**Issuing Office:**

Center for Tobacco Products

United States

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May 31, 2023

**WARNING LETTER**

Dear Kenny Sy, Christopher Sy and Vinh Sy:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed the website <https://www.elementvape.com> and determined that electronic nicotine delivery system (ENDS) products listed there are offered for sale or distribution to customers in the United States.

Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), these products are tobacco products because they are made or derived from tobacco or contain nicotine from any source, and are intended for human consumption. Certain tobacco products, including ENDS products, are

subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)) and 21 C.F.R. § 1100.1, and are required to be in compliance with the requirements in the FD&C Act.

Please be aware that, on March 15, 2022, the President signed legislation to amend the FD&C Act to extend FDA's jurisdiction to products "containing nicotine from any source," not just nicotine derived from tobacco. See Consolidated Appropriations Act, 2022, Public Law 117-103, Division P, Title I, Subtitle B. Specifically, this legislation expanded the definition of "tobacco product" under section 201(rr) of the FD&C Act (21 U.S.C. § 321(rr)) to include products containing nicotine from any source. Tobacco products, including ENDS products, containing nicotine from any source, must be in compliance with the FD&C Act and its implementing regulations. For more information, please see <https://www.fda.gov/tobacco-products/ctp-newsroom/requirements-products-made-non-tobacco-nicotine-take-effect-april-14>.

Generally, to be legally marketed in the United States, the FD&C Act requires "new tobacco products" to have a premarket authorization order in effect. A "new tobacco product" is any tobacco product that was not commercially marketed in the United States as of February 15, 2007, or any modified tobacco product that was commercially marketed after February 15, 2007 (section 910(a) of the FD&C Act; 21 U.S.C. § 387j(a)). Generally, a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. § 387j(c)(1)(A)(i)) is required for a new tobacco product unless (1) the manufacturer of the product submitted a report under section 905(j) of the FD&C Act (21 U.S.C. § 387e(j)) and FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act) or (2) the manufacturer submitted a report under section 905(j)(1)(A)(ii) of the FD&C Act (21 U.S.C. § 387e(j)(1)(A)(ii)) and all modifications are covered by exemptions from the requirements of substantial equivalence granted by FDA under section 905(j)(3) of the FD&C Act (21 U.S.C. § 387e(j)(3)).

### **New Tobacco Products Without Required Marketing Authorization are Adulterated and Misbranded**

Our review of the website <https://www.elementvape.com> revealed that you offer for sale or distribution to customers in the United States the following ENDS products that lack a marketing authorization order: Hyde Rebel, Hyde Retro, and Hyde Edge.

These ENDS products are new tobacco products because they were not commercially marketed in the United States as of February 15, 2007. These products do not have an FDA marketing authorization order in effect under section 910(c)(1)(A)(i) of the FD&C Act and are not otherwise exempt from the marketing authorization requirement. Therefore, these products are adulterated under section 902(6)(A) of the FD&C Act. In addition, these products are misbranded under section 903(a)(6) of the FD&C Act because a notice or other information respecting these products was not provided as required by section 905(j) of the FD&C Act.

### **Conclusion and Requested Actions**

FDA has determined that your firm markets new tobacco products lacking premarket authorization in the United States. All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA's discretion.

For a list of products that received marketing granted orders, please visit our website:

<https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#PMTAView%20all%20marketing%20granted>.

The violations discussed in this letter do not necessarily constitute an exhaustive list. You should address any violations that are referenced above and promptly take any necessary actions to bring the tobacco products you offer for sale or distribution in the United States into compliance with the FD&C Act. It is your responsibility to ensure that these tobacco products and all related labeling and/or advertising on this website, on any other websites (including e-commerce, social networking, or search engine websites), in any other media in which you advertise, and in any retail establishments comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to address any violations of the FD&C Act, 21 U.S.C. § 301 et seq., and implementing regulations relating to tobacco products including the tobacco regulations in 21 C.F.R. Parts 1140, 1141, and 1143, may lead to regulatory or legal action, including, but not limited to, civil money penalties, seizure, and/or injunction. However, this Warning Letter does not constitute "written notice" for purposes of section 303(f)(9)(B)(i)(II) of the FD&C Act. Please note that tobacco products offered for import into the United States that appear to be adulterated or misbranded may be detained or refused admission.

Please submit a written response to this letter within 15 working days from the date of receipt describing your actions to address any violations and bring these products into compliance, including the dates on which you discontinued the violative sale and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act. If you believe these products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. This letter notifies you of our findings and provides you with an opportunity to address them. You can find the FD&C Act through links on FDA's homepage at <http://www.fda.gov>. (<http://www.fda.gov>) ↗ (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

Please note your reference number, RW2301905, in your response and direct your response via email at [CTPCompliance@fda.hhs.gov](mailto:CTPCompliance@fda.hhs.gov) and to the following address:

DPAL-WL Response, Office of Compliance and Enforcement  
 FDA Center for Tobacco Products  
 c/o Document Control Center  
 Building 71, Room G335  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

If you have any questions about the content of this letter, please contact Bryan Hills at (301) 796-9367 or via email at [CTPCompliance@fda.hhs.gov](mailto:CTPCompliance@fda.hhs.gov).

Sincerely,  
 /S/

Ann Simoneau, J.D.  
 Director  
 Office of Compliance and Enforcement  
 Center for Tobacco Products

**VIA UPS and Electronic Mail**

cc:

## FDA NEWS RELEASE

## FDA Conducts Retailer Inspection Blitz, Cracks Down on Illegal Sales of Popular Disposable E-cigarettes

For Immediate Release:

May 31, 2023

Español (<https://www.fda.gov/news-events/press-announcements/la-fda-lleva-cabo-una-campana-de-inspeccion-de-minoristas-y-toma-medidas-energicas-contra-la-venta>)

Today, the U.S. Food and Drug Administration issued [warning letters](https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products) to 30 retailers, including one distributor, for illegally selling unauthorized tobacco products. The unauthorized products were various types of Puff and Hyde brand disposable e-cigarettes, which were two of the most commonly reported brands used by youth e-cigarette users in 2022. The Puff products include Puff Bar. Today's action underscores the agency's unwavering commitment to addressing the role retailers and distributors of unauthorized tobacco products play in this concerning public health issue facing America's youth.

**“Protecting our nation’s youth from tobacco products – including disposable e-cigarettes – is a top priority for the FDA,” said FDA Commissioner Robert M. Califf, M.D. “We’re committed to holding all players in the supply chain – not just manufacturers but also retailers and distributors – accountable to the law.”**

Today's warning letters are a result of a nationwide blitz to crack down on the sale of unauthorized e-cigarettes that are popular with youth – specifically Puff and Hyde products. The blitz included investigations of hundreds of retailers and distributors across the country. All products cited in the warning letters are disposable e-cigarettes, which are the most commonly used e-cigarette product type among youth. Puff Bar and Hyde were the first and third most popular brands used by youth who reported using e-cigarettes, according to the [2022 National Youth Tobacco Survey](https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey). Among youth e-cigarette users, about 20 percent reported usually using Puff Bar or Hyde brand products in 2022.

**“Since becoming director of CTP, I’ve been crystal clear that FDA will not stand by while retailers and distributors seek to profit off illegally selling products that are well-known to appeal to youth,” said Brian King, Ph.D., M.P.H., director of the FDA’s Center for Tobacco Products. “Retailers and distributors play a key role in keeping unauthorized tobacco products off the shelves, and if they fail to do so, we’re committed to taking appropriate action.”**

When e-cigarettes lack a marketing authorization order from the FDA, selling or distributing them to consumers in the U.S. is prohibited under the Federal Food, Drug, and Cosmetic Act. The FDA generally sends warning letters the first time an inspection or investigation reveals a violation of the law, and recipients are given 15 working days to respond with the steps they’ll take to correct the violation and to prevent future violations. A majority of recipients of warning letters voluntarily correct the stated violation. However, failure to promptly correct the violations can result in additional FDA actions such as an injunction, seizure and/or civil money penalties. In addition to today's actions among retailers, the FDA issued a [warning letter to an importer of Puff Bar](https://www.fda.gov/news-events/press-announcements/new-data-show-more-25-million-us-youth-currently-use-e-cigarettes) in October 2022; that investigation remains ongoing.

To date, the FDA has authorized [23 tobacco-flavored e-cigarette products and devices](https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders). These are the only e-cigarette products that currently may be lawfully sold in the U.S. The distribution or sale of unlawfully marketed products is subject to enforcement action.

The FDA remains steadfast in its commitment to protecting youth from the harms of tobacco products by ensuring illegal products are not marketed, sold, or distributed. These efforts include ongoing surveillance of the marketplace to identify violative products, including existing and emerging disposable e-cigarette products.

In February, FDA [filed the agency's first civil money penalty complaints](https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#5) against four e-cigarette manufacturers; to date, FDA has filed civil money penalty complaints against ten e-cigarette manufacturers. And in October 2022, the first [complaints for permanent injunctions were filed](https://www.fda.gov/news-events/press-announcements/fda-doj-seek-permanent-injunctions-against-six-e-cigarette-manufacturers) against six e-cigarette manufacturers. From January 2021 through May 2023, FDA issued more than 560 warning letters. All of these actions are part of FDA's standing compliance and enforcement portfolio, and the latest counts of these actions will continue to be reported on a routine basis. FDA will continue to take action against anyone making, distributing, importing, or selling unauthorized e-cigarette products, especially those most used by youth.

## Related Information

- [Warning Letters](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)
- [Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products](https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products)
- [Results from the Annual National Youth Tobacco Survey](https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey)

###

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

## Inquiries

### Media:

✉ [Abby Capobianco](mailto:abigail.capobianco@fda.hhs.gov)

📞 240-461-9059

### Consumer:

📞 888-INFO-FDA

Was this helpful?

Yes

No

🔗 [More Press Announcements \(/news-events/newsroom/press-announcements\)](/news-events/newsroom/press-announcements)

# **EXHIBIT C**

Hyde Disposables

Case 1:23-cv-05880-LLS Document 42-1 Filed 10/16/23 Page 22 of 157

hydedisposables.com/page.php

Hyde

HOMEPRODUCTSWHOLESALERECHARGE

COLOR RECHARGE  
ICON RECHARGE  
PLUS RECHARGE  
EDGE RECHARGE  
REBEL RECHARGE  
RETRO RECHARGE  
COLOR  
COLOR PLUS  
CURVE MAX  
CURVE PLUS  
EDGE  
ORIGINAL

VALIDATING  
HYDE AUTHENTICITY

Attempts at replicating Hyde products has caused an unfortunate possibility of finding fake Hyde products on the market. To ensure quality, use the Hyde authenticator to validate your Hyde products.


VALIDATE

THE HYDE LINE-UP

https://www.hydedisposables.com/page.php

Type here to search

69°F Sunny 3:41 PM 10/12/2023



SO MANY FLAVORS!

Not only does Hyde boast an impressive range of flavored products, they are constantly growing it! From new fruit combinations, to menthol & tobacco collections; there's a Hyde perfect for your tastes.

# **EXHIBIT D**

Learn more about [LSEG](#)

Healthcare & Pharmaceuticals | Regulatory Oversight

## Insight: New 'candy' e-cigs catch fire after U.S. regulators stamp out Juul's flavors

By Chris Kirkham, Arriana McLymore and Gigi Zamora

August 16, 2022 6:13 AM EDT · Updated a year ago



My View Following Saved



[1/4] Flavored e-cigarette products are seen on a store shelf in Raleigh, North Carolina, U.S., June 23, 2022. REUTERS/Arriana McLymore  
[Acquire Licensing Rights](#)



< Companies >



Altria Group Inc

Follow

RALEIGH, N.C., Aug 16 (Reuters) - Since 2016, the U.S. Food and Drug Administration has sought to crack down on fruity, sweet-flavored e-cigarettes that hook teenagers on nicotine.

But at least 20 brands continue to sell China-made disposable devices with kid-friendly flavors such as "peach blueberry candy" and "pineapple strawnana" at liquor stores, smoke shops and convenience stores in the United States, Reuters has found.

Flavored disposable vaping devices account for one-third of U.S. e-cigarette sales, up from less than 2% three years ago, according to a Reuters review of retail sales data. Their surge raises questions about the public health agency's failure to rein in the booming flavored e-cigarette market and its ability to enforce its own rules, some critics say.

Findings by Reuters are drawn from a dataset produced by IRI, a Chicago market research firm that uses scanner data and other information to track retail purchases. The IRI dataset, which measures purchases from Jan. 12, 2014, to June 12, 2022, provides a rare look at the rise of disposable flavored-nicotine devices following the FDA's crackdown on Juul Labs Inc, 35%-owned by Marlboro maker Altria Group Inc ([MO.N](#)). [read more](#)

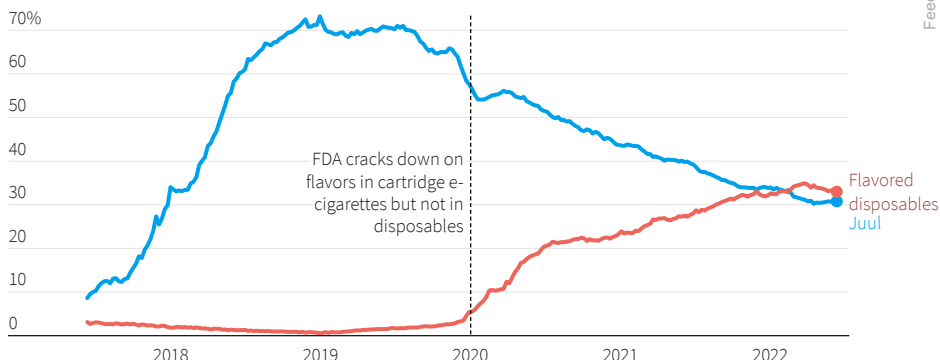
The data shows for the first time that consumers spent more than \$2 billion on the new generation of disposable e-cigarettes over the past year, surpassing Juul's once-leading market share by about 3 percentage points since March.

The data was shared with Reuters by an individual outside IRI, who declined to be identified. An IRI spokesperson said "the information you've received from an outside source" and that the figures should not be attributed to IRI. According to the data, purchases at retailers including more than 30,000 convenience stores.

The FDA said in written responses to questions that it is "deeply committed to addressing the ongoing public health concerns" and "is constantly monitoring the changing marketplace."

## Juul's declining market share vs. flavored disposables

Flavored disposable e-cigarettes overtook Juul in U.S. market share



Source: IRI data seen by Reuters

The FDA in January 2020 banned all flavors except tobacco and menthol in Juul and other cartridge-based e-cigarettes. In June, it sought to ban the sale of all Juul e-cigarettes. The agency has since put its order on hold, saying "there are scientific issues unique to the Juul application that warrant additional review." [read more](#)

Juul referred Reuters to previous statements saying it wants no underage consumers to use its products and that it looks forward to "re-engaging with the FDA" while the ban is on hold.

Sweet-flavored, disposable e-cigarettes began flooding the market in 2020, trying to capitalize on the former popularity of Juul's cartridge-based device. Both varieties vaporize a liquid that contains nicotine, the addictive chemical that gives smokers a rush. Both contain roughly equal concentrations of nicotine.

Disposable devices, which are pre-filled and priced at \$15 to \$25, can have five to 20 times the amount of liquid as a Juul cartridge, based on visits Reuters made to nine retailers selling both. Some products advertise that a user can take thousands of puffs of a single device. In contrast, a Juul, priced at roughly \$10, requires users to add separate cartridges, or pods, of nicotine-laced liquid, priced at \$20 to \$25 per four-pack.

### MILLIONS SPENT WEEKLY ON TOP SELLERS

Three brands - Kangvape Onee Stick, Esco Bars and Breeze Smoke Breeze Pro - rang up weekly sales of more than \$3 million apiece as of June 12, according to the data.

Representatives of Esco Bars and Breeze Smoke said their products contain synthetic nicotine, a version of the addictive drug that is not derived from tobacco plants and was not under FDA's jurisdiction until Congress acted earlier this year. Both companies told Reuters they applied for FDA authorization in 2022.

The FDA declined to disclose the names of synthetic nicotine products that applied.

Darrell Suriff, CEO at Pastel Cartel, the Texas company that makes Esco Bars, said it spent nearly \$3 million preparing applications to the FDA. Firms like his that try to follow the rules should not be penalized, he said: "There's a lot of bad players in the industry ... We're not one of them."

Jon Glauser, chief strategy officer for Hyde, in Buffalo, New York, another disposable brand with synthetic nicotine and sales of nearly \$3 million per week, said he understands critics' concerns that sweet-flavored e-cigarettes appeal to teens, potentially addicting them. But adults "really do like flavors," he said.

Representatives at privately held Shenzhen Kangvape Technology Co did not respond to requests for comment.

## FILLING A 'SWEET' VOID

Juul popularized e-cigarettes among teenagers starting in 2017. Juul's cachet with teens faded after 2019 when it pulled mango, mint and fruit flavors under regulatory pressure, leaving room for dozens of other brands to step in. As sales of flavored disposable devices have soared, Juul's U.S. market share fell to about 30%, from more than 70% in 2018 and 2019, according to the data.

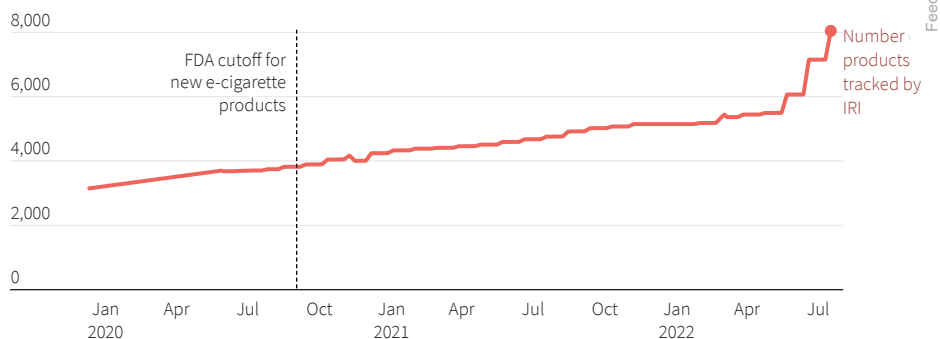
At Luxury Tobacco & Vape in Raleigh, North Carolina, a display for disposable Elf Bar recently offered more rainbow candy. Juul occupied just a fraction of the shelf. Juul declined to comment on the display. Elf Bar did not respond to requests for comment.

According to FDA rules, e-cigarettes cannot be sold in the United States unless their makers submitted scientific data demonstrating why their products benefit public health. E-cigarettes containing synthetic nicotine had until last year been exempt from the rule.

Reuters provided the FDA with a list of more than two-dozen flavored devices that the news agency found in an FDA list of products that filed applications by 2020.

## E-cigarettes by the numbers

The number of vaping products have boomed despite an FDA ban on new market entrants in September:



Source: IRI data seen by Reuters

The FDA declined to answer questions about whether the products Reuters identified had applied for the required authorizations.

An FDA spokesperson pointed to the agency's website, which stated: "Our compliance and enforcement work is a multi-step process that cannot happen overnight."

Mitch Zeller, who retired in April as the director of FDA's tobacco unit, told Reuters there could be gaps on its list because the FDA needed cooperation from applicants in order to publicly list them.

"Is FDA going to catch every single violation of the statute? No," Zeller said, though he said targeting manufacturers that have not applied is FDA's "number one priority."

The agency said on its website on Aug. 3 that "it is illegal" to sell any e-cigarettes using synthetic nicotine without its authorization. As of Aug. 15, the FDA had not granted authorization to any of them.

## SEIZURES

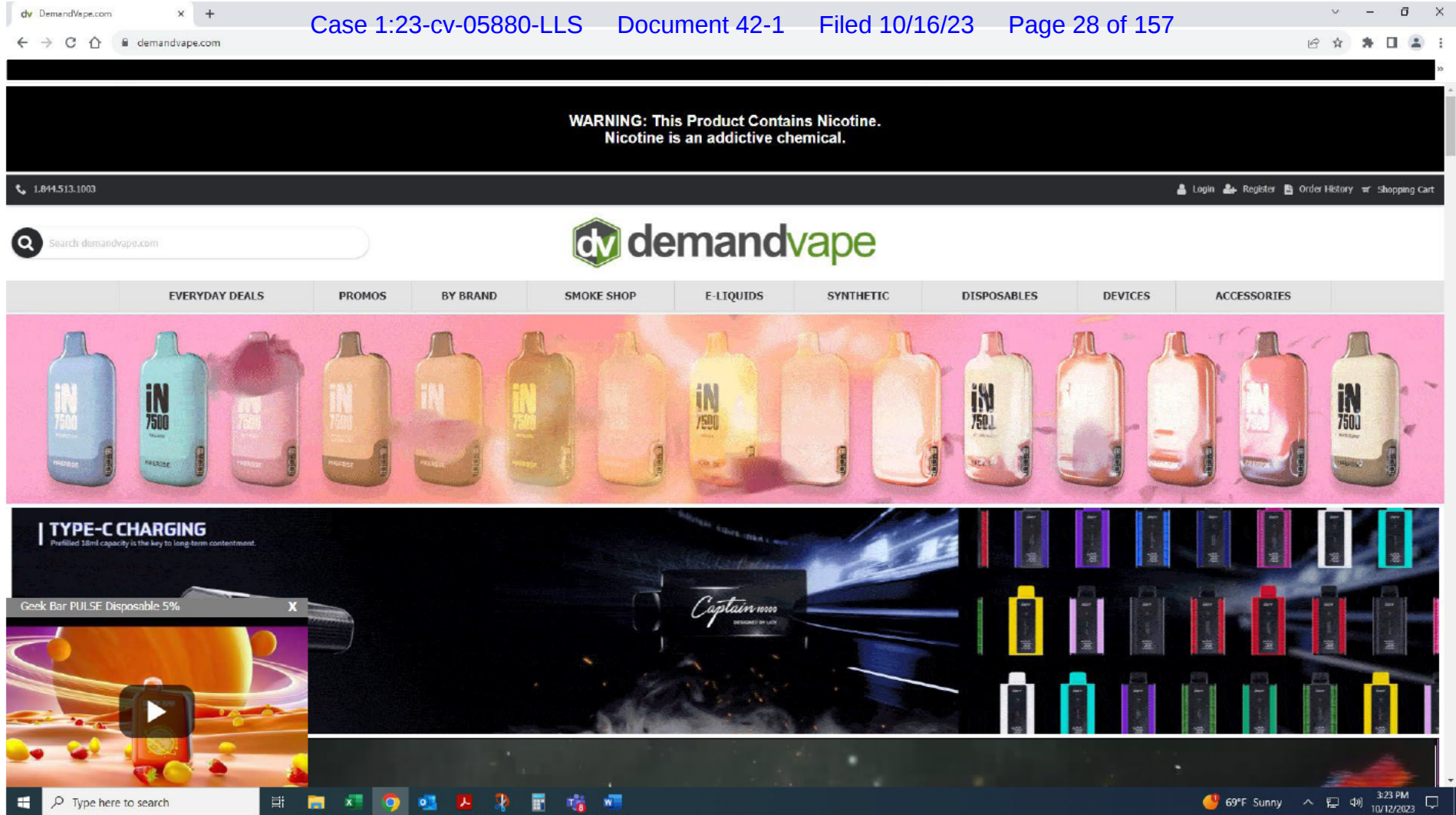
Alex Morrin, 19, used Juul starting in 2017 when he was a high school freshman in the Tampa, Florida, area, drawn to its "fruit," "creme" and "mint" flavors. After Juul eliminated those flavors, Morrin began buying fruity, sweet-flavored disposable e-cigarettes, such as Cali Plus and HQD Cuvie Plus, made by Cali Pods and HQD Tech USA, both based in Florida. "They just tasted better, and there were more flavors," he said. "They're still all out there, and easy to get."

Cali Pods and HQD did not respond to requests for comment.

After he began using e-cigarettes, he suffered headaches and nausea, then seizures that sent him to the hospital six times between January 2020 and last November. Morrin and his mother, Winna Morrin, said he had never experienced seizures before his e-cigarette addiction. Winna Morrin provided hospital records corroborating the seizures. Researchers have established no definitive link between vaping and seizures.

The FDA told Reuters it is seeking to understand whether the devices' "nicotine content or formulation may contribute to seizures." Most reports of seizures from e-cigarettes come from youth, or young adult, users, the FDA said.

# **EXHIBIT E**



DemandVape.com (October 12, 2023)


WARNING: This Product Contains Nicotine.  
Nicotine is an addictive chemical.

1.844.513.1003

Login Register Order History Shopping Cart

Search demandvape.com



EVERYDAY DEALS	PROMOS	BY BRAND	SMOKE SHOP	E-LIQUIDS	SYNTHETIC	DISPOSABLES	DEVICES	ACCESSORIES
 0mg Nicotine Disposables 7 Daze ATR Air Bar / 2027 Air Factory Airis NEO Aloha Sun Anarchist Bad Drip BIFF BAR Binaries Cabin (HorizonTech) BLOK BOBO BOT-IT Boulder Vape Cali Pods Caliburn Bar Candy King Cloud Nurdz Cold Steel CUBE CZAR Death Row Vapes DHOSE Bar	EBCREATE / LostMary / FunkyLands Enou Bar Esco Bars Fifty Bar Firerose Flum FrioBar Fruitia / Jus Bar Full Send Vapor Geek Bar GIMI Glamee Gost Vapor Grumpy Gumi Bar Hero Hotbox Humble Hyde HYPPE ICEWAVE Joy Bar Immortal by Hulk Hogan InneVape Innokin	JuNo KADOBAR KangVape KROS Lost Vape / Orion Bar Lucid LUFFBAR Lykcan (Belo) M.Terk Meta Drop Metaku MINTOPIA MNKE Bars Monster Bar MoodBar MoTi Mr. Fog Mr. Freeze Mrlt Pice Myle Naked 100 Nicless by Vape More NOMS Novo Bar Nuubez	Pacha Mama Packwoods PHUN Pod Juice Pod Pocket Propaganda Prophet Premium Blends Pyne Pod Pyro Tech Quawins Rab Beats RAZ Ruthless SaltBae50 Sea Sili Box SILKY SKWEZED Smack Snoopy Smoke SnowWolf So Soul Spaceman SpaceMax SWFT	Tyson Vaal Vapetasia Verse Bar VIHO Vozol Wotofo Yo Bar Yogi Bar YOVO ZERØ ZoVoo	  <a href="https://demandvape.com/disposables">https://demandvape.com/disposables</a>	 		

https://demandvape.com/disposables

Type here to search

69°F Sunny

3:26 PM  
10/12/2023

DemandVape.com (October 12, 2023)

**WARNING: This Product Contains Nicotine. Nicotine is an addictive chemical.**



Product Code: 50498  
Availability: **In Stock**

In Stock Options		
+ 50498		
	Blue Razz Ice SKU: 50499	<div>- 0 +</div>
	Watermelon Bubble Gum SKU: 50500	<div>- 0 +</div>
	Mango Peach Watermelon SKU: 50501	<div>- 0 +</div>
	Mint Mojito SKU: 50502	<div>- 0 +</div>

15 / 19

Firerose IN7500 Disposable 5% (Display Box of 5) (Master Case of 200)

WARNING: This Product Contains Nicotine.

←

→

Type here to search

69°F Sunny 3:33 PM 10/12/2023

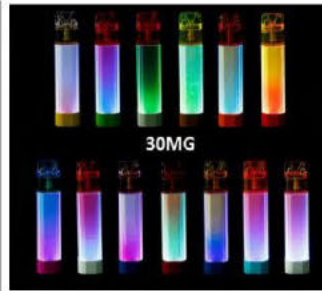
**WARNING: This Product Contains Nicotine.  
Nicotine is an addictive chemical.**



Hyde N-Bar Mini 2500 Puffs \*10 Pack\* (Master Case of 260)



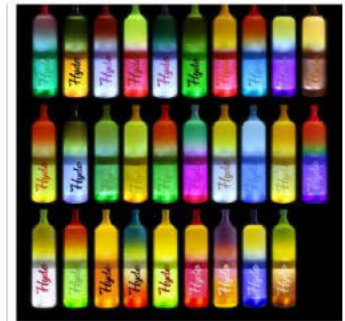
Hyde Mag RECHARGE 4500 Puffs \*10 Pack\* (Master Case of 260)



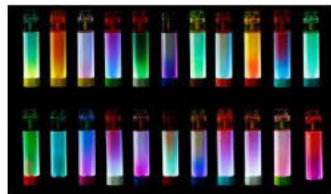
Hyde Edge RAVE Recharge \*\*\*30MG\*\*\* 4000 Puffs \*10 Pack\* (Master Case of 300)



Hyde N-Bar RECHARGE 4500 Puffs \*10 Pack\* (Master Case of 260)



Hyde Retro RAVE Recharge 5000 Puffs \*10 Pack\* (Master Case of 300)



Hyde Edge RAVE Recharge 50mg 4000 Puffs \*10 Pack\* (Master Case of 300)



Hyde Color RECHARGE 3000 Puffs (Master Case of 320)



Hyde Edge Singles 50mg 1500 Puffs (10 Count Bulk Box) (Master Case of 300)



Hyde Edge Singles \*\*\*30MG\*\*\* 1500 Puffs (Master Case of 300)



Hyde Retro RECHARGE 4000 Puffs \*10 Pack\* (Master Case of 300)

# **EXHIBIT F**

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
FORT PIERCE DIVISION  
CASE NO. 22-cv-81576-CANNON

VPR BRANDS, LP,

Plaintiff,  
vs.

FORT PIERCE, FLORIDA

DECEMBER 8, 2022

SHENZHEN WEIBOLI TECHNOLOGY CO.,  
LTD. (ELF BAR), YLSN DISTRIBUTION  
LLC, ECTO WORLD LLC, SAFA GOODS LLC  
D&A DISTRIBUTION LLC, UNISHOW  
(U.S.A.), INC., SV3 LLC, AND  
KINGDOM VAPOR, INC.,

PAGES 1 - 209

Defendants.

TRANSCRIPT OF PRELIMINARY INJUNCTION HEARING  
BEFORE THE HONORABLE AILEEN M. CANNON  
UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFFS: JOEL B. ROTHMAN, ESQ.  
LAYLA NGUYEN, ESQ.  
MARION QUINTERO, ESQ.  
SRIPLAW, P.A.  
21301 Powerline Road, St. 100  
Boca Raton, Florida 33433

FOR THE DEFENDANTS: ERIC HEYER, ESQ.  
KRUPA PATEL, ESQ.  
MICHELLE LI, ESQ.  
CARRIE SHUFFLEBARGER, ESQ.  
ANNA STRESSENGER, ESQ.  
Thompson Hine  
1919 M Street NW, Suite 700  
Washington, D.C. 20036  
TUCKER CROWLEY MOTTA, ESQ.  
McDowell Hetherington, LLP  
2385 NW Executive Center Dr., Suite 400  
Boca Raton, Florida 33433

REPORTED BY: DIANE M. MILLER, RMR, CRR, CRC  
 Official Court Reporter  
 United States District Court  
 101 South U.S. Highway 1  
 Fort Pierce, FL 34950  
 (772) 467-2337  
 diane\_miller@flsd.uscourts.gov

**I-N-D-E-X**

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1 returning home or whatever else you have going on.

2 MR. HEYER: An hour and 15 would be fine, given our  
3 travel plans.

4 MR. ROTHMAN: That's fine, Your Honor.

5 THE COURT: We will be in recess until ten til 2:00,  
6 so 1:50 -- no? All right, I'm not good at math.

7 Okay, there we go, see you all after lunch.  
8 Anything further before we break?

9 MR. ROTHMAN: Just if we can get access to the  
10 attorneys's conference rooms, please.

11 THE COURT: Certainly, we will make that available to  
12 you.

13 MR. ROTHMAN: Thank you.

14 (A lunch recess was had at 11:39 a.m.; proceedings  
15 resumed at 12:55 p.m.)

16 THE COURT: Nice to see you again, you may be seated.

17 I hope you had a nice lunch. Let's resume,  
18 Mr. Heyer, please call your next witness.

19 MR. HEYER: The Defense calls Jon Glauser, Your  
20 Honor.

21 THE COURT: Please remain standing to be sworn, sir.

22 JON GLAUSER, DEFENSE WITNESS, SWORN

23 THE COURTROOM DEPUTY: Please have a seat and then  
24 state and spell your first and last name for the record.

25 THE WITNESS: My name is Matthew Jonathan Glauser,

1 G-L-A-U-S-E-R.

2 MR. HEYER: May I proceed, Your Honor?

3 THE COURT: Yes, please.

4 MR. HEYER: Thank you.

5 DIRECT EXAMINATION

6 BY MR. HEYER:

7 Q Mr. Glauser, where do you work?

8 A I work at Ecto World, LLC, also known as Demand Vape.

9 Q And what is your title with -- I'll refer to it as Demand  
10 Vape, what is your title with Demand Vape?

11 A I am the chief strategy officer and cofounder.

12 Q And are you one of the owners of Demand Vape?

13 A I am.

14 Q Okay. Where is Demand Vape located?

15 A In Buffalo, New York.

16 Q What is the nature of Demand Vape's business?

17 A We distribute vape products throughout the entire country  
18 and some internationally.

19 Q And when you say vape products, do you mean electronic  
20 cigarettes?

21 A I do.

22 Q Approximately how many employees does Demand Vape have?

23 A We have approximately 283, I believe, total.

24 Q Can you explain the history a little bit of when and how  
25 Demand Vape was founded.

1 A Yes. Back in 2009, I quit smoking using a vaporizer, so I  
2 took a trip to China one way, I stayed there for about six  
3 months, met all of the manufactures, did some marketing  
4 research, came back and started the business with my two  
5 partners and got into distribution of open systems and some  
6 single lights that were around back then and went from there,  
7 and officially opened in 2011.

8 Q So is it fair to say at this point that you have  
9 approximately 13 years of experience with the electronic  
10 cigarette industry?

11 A Professional experience, yes; personal, even longer.

12 Q Okay. Based on your knowledge and experience, how old is  
13 the electronic cigarette industry, at least in the United  
14 States?

15 A It started in approximately 2007 in China, and it came to  
16 the United States shortly thereafter, so almost 15 years old.

17 Q Okay. Would it be fair to say you got in almost on the  
18 ground floor of the industry in the United States?

19 A In the United States, absolutely, yes.

20 Q If you have an idea, how many different electronic  
21 cigarette products does Demand Vape sell?

22 A We sell about 30,000 skews.

23 Q Can you explain what a skew is, just for the record?

24 A A skew is -- it could be it's an individual product, but  
25 there could be a product category and each product under that

1 category is an individual skew.

2 Q Okay. And in how many states does Demand Vape sell its  
3 products?

4 A Forty-nine states.

5 Q Do you have an estimation as to how many retailers or  
6 retail customers nationwide Demand Vape sells to?

7 A On average, about 5,000.

8 Q Okay. Would it be fair to say Demand Vape is one the  
9 largest distributors of electronic cigarettes in the United  
10 States?

11 A To my knowledge, yes. There is no concrete metric to say  
12 that, but to my knowledge, yes.

13 Q And based on your experience in the industry, could you  
14 explain how the channels of distribution for electronic  
15 cigarettes work.

16 A Yeah, I'm just going to mirror what the prior witness said,  
17 you know. There's suppliers in Shenzhen, China, that's where  
18 99 percent of e-cigarettes are made. We form a relationship  
19 with them, buy it from them either as a master distributor or  
20 distributor.

21 In my case, we primely sell directly to the vape  
22 shops, smoke shops and convenience stores, but we do master  
23 distribute a lot of products as well.

24 Q Did there come a time over this last summer where you  
25 became aware of a cease and desist letter that was sent by

1 VPR's counsel relating to ELFBAR products?

2 A Yes.

3 Q Prior to that time, had you ever heard of any electronic  
4 cigarettes branded as ELF?

5 A I have not, no.

6 Q Before this lawsuit was filed, had you ever heard of the  
7 Plaintiff, VPR Brands?

8 A I have, only to the extent that they have been involved in  
9 a lot of litigation regarding patent issues.

10 Q Did there come a time when Demand Vape started distributing  
11 ELFBAR brand electronic cigarettes?

12 A Yes, that time would be about October 2021.

13 Q Okay. And did there come a time when, in your observation,  
14 the ELFBAR electronic cigarettes became more popular?

15 A Yes. So I would say the spring of 2022 is when they really  
16 peaked in their popularity, and it has only been growing ever  
17 since.

18 Q How would you rank the popularity of the ELFBAR brand of  
19 electronic cigarettes nationwide in the United States today?

20 A I would unequivocally say across all categories, end  
21 products, they are number one in the United States.

22 Q Do you believe more of those are sold even than RJ  
23 Reynolds' Vuse products found in many convenience stores?

24 A Yes, I do believe that, in fact, to be the case.

25 Q And do you believe that they are -- more of them are likely

1 sold than Juul electronic cigarettes that are sold in  
2 convenience stores?

3 A I could definitively tell you that they are, yes.

4 Q How much, maybe on a percentage basis, of Demand Vape's  
5 overall revenues do the ELFBAR electronic cigarettes represent?

6 A Because we have such a vast business, it's like it changes  
7 from time to time. So it could be anywhere from about  
8 25 percent to 35 percent of our overall revenue.

9 Q Just go slowly, Mr. Glauser, for the court reporter.

10 A I apologize.

11 I'm sorry, Your Honor.

12 BY MR. HEYER:

13 Q As a result of this lawsuit, are you familiar with VPR  
14 Brands' auto concealer ELF electronic cigarette?

15 A I am.

16 Q Okay. Now, there has been -- you were present for the  
17 testimony on the previous day of the hearing via Zoom, were you  
18 not?

19 A That is correct.

20 Q Okay. And do you recall that there was a point made by VPR  
21 about the size and the shape of the ELFBAR electronic  
22 cigarettes being similar to those of their auto concealer  
23 product, do you recall that?

24 A I do you recall that, yes.

25 Q In your experience, are there any other electronic

1 cigarettes available in the marketplace that are also of a  
2 similar size and shape?

3 A Due to the nature of how this industry has evolved over the  
4 years, I would say that is probably the most common size and  
5 shape that's available and the most popular size and shape  
6 available in the industry today.

7 Q Have you ever heard, in your experience, the ELFBAR brand  
8 electronic cigarettes ever referred to by anyone in the  
9 industry as ELF?

10 A I have not, no.

11 Q Okay. And in your position over the years, do you  
12 frequently attend trade shows for the electronic cigarette  
13 industry?

14 A Yes. I -- probably on average, over the last six to seven  
15 years, about 50 trade shows a year, I would say.

16 Q Okay. Do you regularly visit vape shops?

17 A Yes, very regularly.

18 Q Okay. How about convenience stores that handle or that  
19 sell electron cigarette products?

20 A Yes, I also visit convenience stores.

21 Q Do you have an estimate as to how many brick and mortar  
22 retail outlets you would visit that sell electronic cigarette  
23 products in a given year?

24 A This is an estimate, it being -- maybe approaching a  
25 thousand.

1 Q Okay. And have you ever seen, in your experience, any of  
2 VPR's ELF branded products advertised or offered for sell in  
3 any of these outlets?

4 A I have not, no.

5 Q Do you visit the websites of other distributors in your  
6 position?

7 A From time to time, yes.

8 Q Okay. Have you ever seen any of VPR's ELF branded  
9 electronic cigarettes advertised or offered for sale on any  
10 other distributors' websites?

11 A I have not, no.

12 Q To your knowledge, have any of your customers ever inquired  
13 about selling VPR's ELF branded electronic cigarettes?

14 A They have not, and in my position, I have 32 sales people  
15 who are constantly requesting products based on demand, and not  
16 a single one of them has ever requested that product.

17 Q Okay. Have you ever seen VPR's ELF branded products  
18 advertised online?

19 A I have not, no.

20 Q Has anyone, in your experience in the industry, whether  
21 they are your customer or your sales rep or anyone else, ever  
22 indicated any confusion between VPR's ELF branded electronic  
23 cigarettes and ELFBAR products?

24 A No, I have not.

25 Q Are you aware of any confusion among consumers between

1 ELFBAR and VPR's ELF branded electronic cigarettes?

2 A I'm not aware. We routinely do surveys with consumers to  
3 get their perception, and it has never come up.

4 Q Okay. Do you think it is likely that such confusion would  
5 exist amongst consumers based on your experience?

6 A In my experience, I would say it is highly unlikely there  
7 is any confusion between the two.

8 Q Why not?

9 A Because the VPR branded ELF is just not known about in any  
10 big enough fashion to cause any confusion, where ELFBAR is by  
11 far the number one selling one in the country.

12 Q How would you describe the target consumer for electronic  
13 cigarettes?

14 A So the target consumer for electronic cigarettes are  
15 generally nicotine addicted adults who want to transition to a  
16 safer alternative to traditional combustible cigarettes.

17 Q Okay. And for vaporizers that use substances other than  
18 nicotine, who would you describe as the target consumers for  
19 those?

20 A I would describe those people mainly recreational,  
21 non-addicted users of alternative products, such as THC, Delta  
22 8, CBD and the like.

23 Q Can you explain what THC, Delta 8 and CBD are.

24 A Yeah. So all of those substances are derived from the  
25 cannabis plant, different variants that are chemically derived,

1 and they perform different functions for different people  
2 depending on how they are consumed.

3 Q Okay. Can you speak to the general popularity of  
4 disposable electronic cigarettes, not necessarily ELFBAR  
5 specifically, but just sort of that subclass?

6 A Yes. So over the years, the disposable category has very  
7 much become like the mainstream staple category of this entire  
8 industry.

9 Q Was that always the case historically?

10 A Absolutely not, no.

11 Q Okay. Can you explain a little bit about the evolution of  
12 what was popular and less popular.

13 A Yeah. So I have the benefit of getting in kind of very  
14 earlier in this industry, and it was actually a very  
15 interesting evolution. It started off with devices that looked  
16 just like a cigarette, held like a cigarette, weighed like a  
17 cigarette.

18 As things progressed, it went to your open type  
19 system, where you refill your own liquids, e-liquids that would  
20 come on to the market and they were very primitive. And as  
21 more time went on, those types of systems, they became, you  
22 know, better electronics, wider range of power, bigger tanks,  
23 and then we kind of transitioned to like the smaller more  
24 streamlined style, but with a more technologically efficient  
25 way of using them, and that brings us back to the disposable

1 type e-cigarette.

2 Q Could you explain, from an ease of use perspective, how  
3 disposables compare to open system products for your typical  
4 consumer of electronic cigarettes.

5 A So in my opinion, I think it's night and day. When you  
6 have an adult cigarette smoker, it is very easy to smoke a  
7 cigarette. You pull a cigarette out of a pack, you put it in  
8 your mouth, light it, you smoke it until it is finished, and  
9 disposables offer that same kind of convenience for those adult  
10 smokers who want to transition, but in a much safer, proven  
11 way, and I think that's why they have gravitated back towards  
12 that type of e-cigarette type device.

13 Q And you're referring to these products as safer. Can you  
14 explain, is there any testing that your company does on the  
15 products that you import and sell from a safety perspective?

16 A Absolutely. So we take safety very seriously, we do  
17 in-house testing through a third party lab on, you know,  
18 specific products, we do random products all the time. We  
19 actually do testing on counterfeits as well.

20 I filed two premarket tobacco applications and --

21 THE COURT REPORTER: Pre what, I'm sorry?

22 THE WITNESS: Premarket tobacco applications, PMTA,  
23 would be the abbreviation, which, you know, that took quite a  
24 bit of time and money. It's a lot of studies to be done, it  
25 gives you very good insight into how these products work and

1 what is involved in them, the chemistry of what they do to the  
2 human body, et cetera.

3 BY MR. HEYER:

4 Q Thank you. And to what would you attribute the increased  
5 popularity of disposables over time?

6 A I think it's honestly a matter of convenience for the  
7 consumer because the easier you make something, especially when  
8 you are transitioning from something that someone is addicted  
9 to, the more likely they are to be able to make that  
10 transition, so I think disposables really help bridge that gap  
11 for your everyday smoker in the convenience factor and it's  
12 much more accessible to the masses.

13 MR. HEYER: Court's indulgence, may I approach to  
14 show the witness Exhibit 22?

15 THE COURT: You may.

16 MR. ROTHMAN: This is 22?

17 MR. HEYER: Yeah.

18 THE COURT: I just have a quick question, before we  
19 get to the financials, on the disposable issue.

20 The actual boxes that we had, I think Defense 19  
21 perhaps, and maybe Plaintiff's -- I can't recall the number for  
22 the Plaintiff's exhibit, but I would like the witness to answer  
23 whether those are disposable.

24 THE WITNESS: Of course, Your Honor.

25 Yes, these are both disposable type e-cigarettes.

1 THE COURT: Okay. You can keep them.

2 THE WITNESS: Thank you.

3 BY MR. HEYER:

4 Q Mr. Glauser, if you could look at Defendants' Exhibit 22,  
5 can you explain to the Court what this is.

6 A This is -- I had my employee pull a report to show our  
7 gross profit and margin on the sales from October '21 to  
8 October '22 on ELFBAR products.

9 (Evidence identified as Defense Exhibit No. 22.)

10 BY MR. HEYER:

11 Q October 2021 until October 2022, is that correct?

12 A That is correct.

13 Q And I see that -- it looks like one of the grand totals did  
14 not show up. Is that the grand total revenue from sales of  
15 ELFBAR products that has the pound signs there?

16 A Yes, that's correct.

17 Q And that number could be derived by adding up all of the  
18 numbers?

19 A Yes.

20 Q And is Exhibit D22 basically a compilation of data prepared  
21 from the company's financial records that are created and  
22 maintained in the normal course of Demand Vape's business?

23 A They are, yes.

24 MR. HEYER: Your Honor, I move the admission of  
25 Defendants' Exhibit 22.

1 THE COURT: Any objection from Plaintiff to  
2 Defendants' 22?

3 MR. ROTHMAN: No, Your Honor.

4 THE COURT: All right. Defendants' 22 will be  
5 admitted without objection.

6 (Evidence admitted as Defense Exhibit No. 22.)

7 BY MR. HEYER:

8 Q In the lower table, as it were, in Defendants' Exhibit 22,  
9 Mr. Glauser, can you explain what that represents there?

10 A So that is our gross profit margin. That does not include  
11 any overhead or any other expenses, that's just the gross  
12 profit after the sales of the product before any other expenses  
13 are involved.

14 Q Okay. And is that calculated into your company's ERP  
15 system?

16 A Yes, that is correct.

17 Q All right. And the numbers over to the right, those are  
18 monthly totals of gross profit for each of the months from  
19 October 2021 to October 2022, is that correct?

20 A Correct.

21 Q How would you characterize if there has been a trajectory  
22 in the sales of ELFBAR products that Demand Vape has sold over  
23 time?

24 A Sure. So it has steadily been going up. The demand is  
25 actually been so high that if you look at this chart, it is a

1 little bit misleading because the numbers reflect the sales,  
2 but if we would have had enough product, those numbers would  
3 actually be much higher, so we were selling it faster than we  
4 could get it in.

5 Q What time period specifically did you have issues with  
6 getting sufficient supply to meet sufficient demand for the  
7 ELFBAR products?

8 A So I would say right after June is when it really became  
9 problematic to get the supply to meet the demand.

10 Q Okay. June of this year?

11 A Of 2022.

12 Q Okay. Have you -- let me ask you this: Do you know  
13 whether ELFBAR has filed any PMTAs for any of its products?

14 A Yes, they have. I always do my due diligence with our  
15 suppliers, not only in the testing of the products  
16 independently, but also in terms of what they have done in  
17 terms of regulatory stuff and they have done a PMTA.

18 Q During the last year or so, have you noticed any other  
19 products enter the marketplace that have ELF as part of their  
20 name, besides ELFBAR?

21 A I have, and most of those -- actually all of those products  
22 come from very un reputable Chinese manufacturers. I would call  
23 them counterfeit products, and they are made at a very low  
24 quality.

25 Q Okay. And when you say that they are counterfeit or low

1 quality, could you explain how you determine that or why you  
2 classify it that way.

3 A Yes, absolutely. I have spent quite a bit of time in  
4 Shenzhen, China over the years. I basically know and have a  
5 good relationship with every manufacturer over there, I mean  
6 legitimate manufacturer. I have been to all of their  
7 facilities, I see how they manufacture everything, and the  
8 people that are sending the counterfeits are your fly-by-night  
9 pop-ups. Places open, start manufacturing, and then move to  
10 another location to evade the Government.

11 I have actually even done testing on some of these  
12 products and the toxic level of metals, for example, would be  
13 off the charts. The harmful -- potentially harmful  
14 constituents of the e-liquid are much, much higher than the  
15 ELFBAR products that are on the market.

16 Q The legitimate ELFBAR products?

17 A Yes, the legitimate ELFBAR products.

18 Q All right. Did you notice whether more of those  
19 counterfeit-type products were being imported into the U.S. and  
20 offered for sale when the supply to be able to supply the  
21 ELFBAR products was not sufficient to meet demand in the summer  
22 of this year?

23 A Yes, absolutely, that is the case. Anytime a demand is not  
24 met, someone fills that demand and the Chinese business model,  
25 the way it is run, is very good at adapting to fill that

1 demand, so it is almost immediate that you see that happen.

2 Q Have you seen that in your experience with other brands,  
3 other than ELFBAR, where there were similar issues of knockoffs  
4 or counterfeits coming out?

5 A Yes, over the years, many, many times. It happened with  
6 Juul, it happened with Hyde, it has happened with almost every  
7 mainstream product that has, you know, gained a big market  
8 share of this industry.

9 Q Are you -- since this litigation has been filed, have you  
10 become familiar with VPR's auto concealer ELF branded product?

11 A Yes.

12 Q Okay. Do you have any firsthand experience in interacting  
13 with FDA with respect to similar products, and what I mean by  
14 similar products are open system vaporizers that are not  
15 explicitly marketed for use with nicotine, in your experience?

16 A I do, yes.

17 Q Could you explain what that experience has been.

18 A So since we import so many products and we distribute so  
19 many products, I deal with FDA on a fairly regular basis. Just  
20 a couple weeks ago, they came and did an inspection on what I  
21 would classify as an almost identical product type in function  
22 and form. They classified it as a tobacco product and I'm  
23 still waiting the determination of the release of that product  
24 from customs.

25 Q So FDA has not released that particular product from

1 customs, is that right?

2 A That is correct, and that means they have regulatory  
3 authority over that product.

4 Q Okay. If the Court were to preliminarily enjoin Demand  
5 Vape from further sales of ELFBAR products, what, if any, would  
6 be the impact on your business?

7 A I would classify it as detrimental given we have so many  
8 employees, and if it makes up, at times, about a third of our  
9 overall profit, you know, that's -- you are approaching 100  
10 employees that I would have to potentially layoff, and a lot of  
11 our employees are actually refugees that are here legally from  
12 Burma.

13 Q In terms of your relationship with customers that buy  
14 ELFBAR products, what would you anticipate would happen if  
15 Demand Vape is enjoined from continuing to sell ELFBAR  
16 products?

17 A It would put a huge strain on some of those customer  
18 relationships that we put a lot of time and energy into over  
19 the years to maintain. One of the best assets of our company  
20 are those customer relationships, it is really what we depend  
21 on to keep our market share.

22 Q Okay. I think there was perhaps a suggestion by VPR's  
23 Counsel that couldn't a distributor like Demand Vape use other  
24 branded products to fill the void if ELFBAR products are not  
25 able to be sold due to an injunction, what would you say to

1 that?

2 A I would say that I can definitively, without a doubt, based  
3 on history and my own experience, say that's equivocally  
4 untrue.

5 When there is a demand for a product and the consumer  
6 is very familiar with that product, they are going to continue  
7 to want to get that product, in some cases even knowing they  
8 are counterfeit products. It is like anything else, they get  
9 tied to the brand, so you can't just switch one product for  
10 another and push a product. There is a supply and demand issue  
11 there that we have no control over.

12 Q Do you remember him showing Mr. Shriteh, I think it was  
13 Plaintiff's Exhibit 25 that had the Puff Bar products --

14 A Yes.

15 Q -- just a little while ago?

16 What can you say with respect to Puff Bar products  
17 and counterfeits, if anything?

18 A So Puff Bar was actually pulled from the market because of  
19 FDA action. They were -- I would classify them as, you know,  
20 in the same category of ELFBAR at one point. About a year and  
21 a half ago in terms of potential sales, they were definitely  
22 number one in the marketplace and they also had a huge  
23 counterfeit problem and no one was able to stop it and the  
24 demand was still there.

25 Q If, in fact, other products from less reputable

1 manufacturers did sort of fill the void, as you have explained  
2 it, would you have any concerns from a public health or safety  
3 point of view related to that?

4 A Absolutely. Just based on my own in-house testing of some  
5 of these products, it would be detrimental to public health,  
6 especially at the numbers we are talking about here entering  
7 the marketplace.

8	Q	Okay.
---	---	-------

9 A You are talking about a situation where people don't know  
10 what they are getting and what they are inhaling into their  
11 lungs.

12 Q I know you mentioned like heavy metals potentially being  
13 something that would be inhaled, is that right?

14 | A That's correct.

15 Q What else have you found from testing some of these  
16 counterfeit products?

17 A So in the statutory requirements of a premarket tobacco  
18 application, you test for harmful and potentially harmful  
19 constituents, which there is an exhaustive list of constituents  
20 that you may find in e-liquid that would qualify as potentially  
21 harmful. We've found levels of nitrosamines, all kinds of  
22 stuff to be quite honest, all across-the-board. Almost  
23 everything that I have seen, FDA doesn't want to see in that  
24 product.

25 Q You found these things in counterfeit products?

1 A Yes, absolutely.

2 MR. HEYER: I move Defendants' Exhibit 22 into  
3 evidence, and I think I'm done.

4 THE COURT: Defense 22 is in evidence.

5 MR. HEYER: Thank you.

6 THE COURT: All right. Any cross?

7 MR. ROTHMAN: Yes, Your Honor.

8 CROSS-EXAMINATION

9 BY MR. ROTHMAN:

10 Q Good afternoon, Mr. Glauser.

11 A Good afternoon.

12 Q You're obviously very passionate about some of these topics  
13 that we have been talking about today.

14 A Yes, I agree with that.

15 Q You are a member of the board of the Vape Technology  
16 Association.

17 A That's accurate, yes.

18 Q And what is the mission of the Vape Technology Association?

19 A The VTA or the Vape Technology Association is a  
20 not-for-profit organization that advocates for what I would  
21 call a safer alternative to products for adults to consume  
22 nicotine in a safer way.

23 Q And when you say products for adults to consume nicotine in  
24 a safer way, we are talking about products like ELFBAR.

25 A Yeah, I would classify ELFBAR as one of those products.

1 Q Your company, Demand Vape, what were the total -- what was  
2 the total revenue earned by Demand Vape in the last year that  
3 you have a full year of revenue for?

4 A Are you asking for a specific product or across-the-board?

5 Q No, I'm asking for overall revenue in dollars and not  
6 profit, total revenue.

7 MR. HEYER: Objection, relevance.

8 THE COURT: Why do you consider that question to be  
9 irrelevant, if you are trying to persuade the fact finder that  
10 a potential injunction would cause irreparable harm?

11 MR. HEYER: The extent of it is getting beyond the  
12 products at issue in this case and given sort of the sensitive  
13 nature of the data, I feel like it is irrelevant, Your Honor,  
14 to ask such a specific question in such a broad manner.

15 THE COURT: I'll overrule the objection. You may  
16 proceed.

17 THE WITNESS: I don't have the numbers in front of  
18 me, I can give you an estimate probably; about five to  
19 600 million.

20 BY MR. ROTHMAN:

21 Q Five to 600 million?

22 A Yes.

23 Q Do you recall testifying on direct that the ELFBAR product  
24 was between 25 to 35 percent of your company's overall revenue?

25 A I do.

1 Q Twenty-five to 35 percent of the overall revenue based on  
2 an estimate of between 500 and 600 million would be in the  
3 nature of several hundred million dollars, right?

4 A I may have misunderstood the question.

5 So I took the gross profit and given we sell a wide  
6 variety of categories, such as hardware open system, where we  
7 make a much lower profit on, the revenue wouldn't reflect  
8 evenly across-the-board. Well, the revenue would, but the  
9 gross profit would not, if that makes sense.

10 Q It doesn't. I'm looking at Exhibit 22 and according to my  
11 math -- I can't tell because the grand total is blocked out  
12 here, but according to my math, the total sum of the revenue  
13 for the ELFBAR product from October '21 to October '22 is on  
14 the order of 128 million or so.

15 A That is correct.

16 Q Okay. So that -- that seems like a smaller percentage of  
17 overall revenue than 25 to 35 percent.

18 A Well, 150 million times four would be 600, so what is that,  
19 600 million.

20 Q Okay. It sounds like, though, we are talking about more in  
21 the nature of maybe 15 to 20 percent of the total revenue today  
22 based on your sales for 2022, right?

23 A As I stated, I don't have an exact number for you, so I'm  
24 estimating.

25 Q And according to Exhibit 22, the sales only began to exceed

1 the ten million dollar a month amount beginning in April of  
2 this year, right?

3 A Yes, that is correct, as per the chart.

4 Q Okay. What was your biggest seller a year ago?

5 A The Hyde brand of products.

6 Q What is the Hyde brand of products, is that a disposable  
7 vape like the ELFBAR?

8 A It is very similar, yes.

9 Q And was it the biggest seller two years ago?

10 A I don't know the exact timeframe, but yes, there was a  
11 point in time where it was the biggest seller.

12 Q Did it hold on to that top spot for more than a couple  
13 years?

14 A No.

15 Q No? I mean, I have been to your website.

16 MR. ROTHMAN: If I can use the video connection, the  
17 HDMI connection. And we will produce a PDF version of this,  
18 Your Honor, to the extent that it would be hard to capture all  
19 of the motion in a PDF, but we will do our best and mark it as  
20 the next exhibit number.

21 BY MR. ROTHMAN:

22 Q Looking at the screen, this is Demand Vape's website, your  
23 company's website, right?

24 A That is correct.

25 Q And we see right front and center there is the ELFBAR

1 product, right?

2 A Yes.

3 Q Above that is the Hyde product, correct?

4 A Correct.

5 Q Okay. To the left of the ELFBAR, what is that product?

6 A Flum probably; yes.

7 Q That product looks very similar to the ELFBAR product, is  
8 it a similar product, does it fall into the same category?

9 A Yes, it is a disposable device.

10 Q Okay. Below the Flum product, there is this product that  
11 looks very similar to the ELFBAR, I can't tell what that is by  
12 bar?

13 A I'm not sure where you are --

14 Q On the left-hand side of the screen, do you see the --

15 A Yep, Biff Bar.

16 Q And below the ELFBAR is the Luffbar.

17 A That's correct.

18 Q To the right of the Luffbar is the Geek Bar.

19 A Is that a question?

20 Q That's another product that's similar to the ELFBAR.

21 A Yes.

22 Q But I just want to make sure we understand each other, you  
23 want this Court to believe that despite the fact that your  
24 company distributes the Luffbar, the Biff Bar, the Geek Bar,  
25 the Flum Pebble, all of which are similar to the ELFBAR, that

1 enjoining the sales of the ELFBAR will lead to a vacuum where  
2 purchasers will end up buying counterfeit ELFBARs that will  
3 harm them, that's your testimony?

4 A That is correct, and I think that testimony is backed by  
5 history and a long pedigree in this industry.

6 Q And I understand you do have a long pedigree in this  
7 industry and I'm not challenging that, but you talked about  
8 surveys that you have done on e-cigarettes. Have those surveys  
9 been produced to us in this case?

10 MR. HEYER: Objection, Your Honor, discovery hasn't  
11 started.

12 THE COURT: All right, sustained.

13 MR. ROTHMAN: Okay.

14 BY MR. ROTHMAN:

15 Q I'm not aware of receiving any surveys that the Defendants  
16 are relying upon, okay. So are there any surveys that you  
17 intend to rely upon that I'm not aware of because you indicated  
18 that that was something that you were basing your testimony on?

19 MR. HEYER: Objection, Your Honor. We haven't even  
20 filed our answers to the complaint yet, this is an expedited  
21 preliminary injunction.

22 THE COURT: All right. Why don't -- I'll sustain the  
23 objection based on the way the question was presented.

24 But Mr. Rothman, if you want to ask the witness about  
25 surveys, you may do so. He did mention in his direct that his

1 company conducts surveys in a general sense, so you can probe  
2 that line of inquiry if you wish.

3 MR. ROTHMAN: Okay.

4 BY MR. ROTHMAN:

5 Q Is there a specific survey done by a specific survey  
6 company on a particular date concerning a particular product  
7 that you're relying upon here today?

8 A No.

9 Q You also referred to testing. Is there specific testing  
10 done on a specific product that you are relying on here today?

11 A Can you rephrase the question, because I'm not sure what  
12 you mean by relying on.

13 Q Well, I want to understand the basis for the position you  
14 are taking that removing ELFBAR is going to harm people, right,  
15 and you said you've done surveys, you have done testing, and  
16 you also referred to situations where there was an FDA hold  
17 placed on a product, it sounded like it was in customs, on an  
18 almost identical product type, and I want to understand what  
19 those specifics are if you are, in fact, asking the Court to  
20 rely upon them.

21 I'm not questioning your experience, I just want to  
22 know, sitting here today, is there something specific that you  
23 want the Court to refer to or is this just -- this is just your  
24 general experience?

25 A I appreciate you clarifying and let me clarify. I wasn't

1 relying on those things in a specific sense to prove that  
2 ELFBAR would be over -- would not get overtaken by something  
3 else.

4 I was relying on those things in a general sense, but  
5 my bigger reliance was on the historical data in sales I have  
6 on other products that were in a similar situation that is  
7 demonstratively proveable.

8 Q The historical data that you have indicates, and I'm  
9 quoting from your testimony on direct, that, quote, "Any time a  
10 demand is not met, someone fills that demand."

11 A That's correct.

12 Q Okay. So isn't it the case and perhaps just as likely that  
13 if the ELFBAR product is not available for purchase, that the  
14 demand for the product will be filled by another product like  
15 one of these other bar products we see on your website?

16 A No, I cannot agree with that statement at all. I don't  
17 think it's just as likely. I think it's much more likely that  
18 it will be filled by counterfeits.

19 Q Okay. And your basis for concluding that is what, other  
20 than this experience that you have told us about, what else?

21 A I gave specific examples such as Juul, Hyde, there are a  
22 couple other products in the past as well that faced similar  
23 situations and in every single one of those situations in the  
24 immediate aftermath -- yes, in time, they were replaced by  
25 other types of products, just as ELF did in this situation.

1 But for -- you know, I don't know the exact time period, but  
2 it's not a negligible time period, it was fulfilled by  
3 counterfeits every single time, that's what I'm relying on.

4 Q How much time are we talking about, because we are looking  
5 at the sales here in Exhibit 22, and I want to understand so  
6 that the Court can make a determination, how much time is it  
7 going to take for the demand for ELFBAR to be filled by other  
8 products and during that time, you say, will be diverted to  
9 counterfeit products; a month, two months, three months, how  
10 much time?

11 A Well, this is speculation on my part, but base based off  
12 history and the other products, anywhere from 40 days to 90  
13 days.

14 Q Okay. So somewhere between 40 to 90 days is when the  
15 absence of the ELFBAR product on the market could potentially  
16 lead people to be purchasing counterfeit product until it is  
17 filled by some other legitimate product seller, for lack of a  
18 better term than legitimate.

19 A That is one possible outcome, yes.

20 THE COURT: So when you refer to this prospect of  
21 purchasing counterfeit, what exactly are you referring to? So  
22 a counterfeit of the ELFBAR would be what exactly in your mind?

23 THE WITNESS: So Your Honor, a counterfeit, how I  
24 define it is something that looks exactly like Exhibit D19  
25 here, that has the same packaging, has the same markings, it

1 looks exactly like the product, but is not made by the original  
2 manufacturer, that's what I describe as a counterfeiter, Your  
3 Honor.

4 THE COURT: Then I have another question about the  
5 surveys, you mentioned them in your direct in relation to the  
6 potential for consumer confusion. Are you aware of any studies  
7 conducted by your company that have actually compared the  
8 prospect of confusion between ELFBAR and ELF products?

9 THE WITNESS: No, we have not done because as I  
10 stated in my previous testimony, I was not aware of the ELF  
11 product line until this lawsuit.

12 THE COURT: Understood, thank you.

13 BY MR. ROTHMAN:

14 Q Thanks. Now, you are aware of my client's company, though,  
15 right?

16 A Yes, as I previously stated, just from hearing of  
17 litigation in the industry.

18 Q But you also sell his products on your website, right?

19 A I'm not -- not that I'm aware of, I don't do the  
20 purchasing, so I don't know.

21 Q Okay. But my client has a few different -- you know my  
22 client has a few different brands it holds trademarks for,  
23 products under the name HoneyStick, are you familiar with that?

24 A No, I did not know your client held the trademark under the  
25 trademark HoneyStick until you just told me, so --

1 Q If we go and we look at your website for brands --

2 MR. ROTHMAN: Where did we see it?

3 (Discussion off the record.)

4 BY MR. ROTHMAN:

5 Q So if we look at Demand Vape under alternative, there's two  
6 HoneyStick products there that my client makes.

7 A Is that a question?

8 Q Well, I'm asking, now that you see that, do you agree that  
9 your company sells products that are made and distributed by  
10 VPR?

11 A To the extent that what you are telling me is accurate,  
12 absolutely, yes.

13 Q There was some testimony about the types of products that  
14 my client sells, these kit products, the ELF products.

15 MR. ROTHMAN: What are we up to?

16 I would like to show the witness what has been marked  
17 as Plaintiff's Exhibit 26.

18 Thank you, sir.

19 BY MR. ROTHMAN:

20 Q You have seen pictures of that product before, maybe you  
21 haven't held one previously, but the product that my client  
22 sells that is marked Plaintiff's Exhibit 26, does that fall  
23 into a category of products that we could find on the Demand  
24 Vape website?

25 A Can you be more specific with the question, what do you

1 mean by category?

2 Q Well, there are many different categories on the Demand  
3 Vape website and if we go to devices, there is a device  
4 category called kits, and if I click on kits, right, we see  
5 devices including -- see this Uwell device that Mr. Hardy (sic)  
6 was testifying about earlier today?

7 A I do.

8 Q Okay.

9 A I don't believe that's the same device though.

10 Q No. It looks somewhat like what we saw in Defendant's  
11 Exhibit 16 or 17 to me, but these products we are looking at  
12 under kits, can you describe for me what these -- perhaps how  
13 these products are different from the ELFBAR product, what are  
14 the attributes of these products?

15 A Yes. A kit is anything that when you buy it, such as what  
16 you just handed me here --

17 Q Okay.

18 A -- across any category, it comes with everything you need  
19 to start vaping minus potentially whatever substance you are  
20 going to put into it.

21 (Evidence identified as Plaintiff's Exhibit No. 26.)

22 BY MR. ROTHMAN:

23 Q Okay. So the product that you are holding there, my  
24 client's ELF product that's been marked as Exhibit 26, that  
25 product is like the products that are listed on your website

1 under the devices kits subsection, correct?

2 A Yes, it's similar, correct.

3 Q Okay. And what about -- well, I'll show you what we will  
4 mark as Plaintiff's Exhibit 27.

5 MR. ROTHMAN: You don't have to get up, if you allow  
6 me to approach the witness.

7 MR. HEYER: Can we see what that is?

8 MR. ROTHMAN: It's the pen battery, it is the  
9 battery.

10 MR. HEYER: Thank you.

11 THE COURT: None of these exhibits yet have been  
12 admitted, correct, Mr. Rothman?

13 MR. ROTHMAN: They were shown before. If necessary,  
14 I can put them in through my client, if there is any objection.  
15 At this point, I'm just showing them to --

16 THE COURT: Okay.

17 MR. ROTHMAN: -- the witness for identification  
18 purposes.

19 THE COURT: Okay.

20 MR. ROTHMAN: Pictures of them have been admitted as  
21 exhibits already, though.

22 THE COURT: Okay.

23 BY MR. ROTHMAN:

24 Q What category would that exhibit fall into, that product,  
25 the device you are holding?

1 A This is a battery.

2 (Evidence identified as Plaintiff's Exhibit No. 27.)

3 BY MR. ROTHMAN:

4 Q Okay. Would you attach something to the battery?

5 A You could, yes.

6 Q Okay. And would that something that you attached to the  
7 battery be a vaporizer that you could put liquid into?

8 A Potentially, yes. There is a -- there is what you call a  
9 510 connection to it, which is the industry standard. So you  
10 can connect almost anything you wanted to this battery that has  
11 a 510 threaded adapter on it.

12 Q Okay. So that 510 threaded adapter could be filled with  
13 nicotine e-liquid, and then it would function like any of the  
14 devices that we saw on the kits site when they were filled,  
15 right?

16 A It would function in a similar manner, yes, it would become  
17 essentially a kit. But this, in and of itself, wouldn't be  
18 considered a kit.

19 Q That's just the battery part you need to attach the  
20 reservoir for the e-liquid to what you refer to as the 510  
21 mouthpiece, correct?

22 A Correct, yes.

23 Q Do you sell those 510 mouthpieces on Demand Vape?

24 A Yeah, I'm sure we do. We sell a ton of different -- you  
25 know, across all categories.

1 MR. ROTHMAN: Is there any objection to the admission  
2 of Exhibits 26 and 27?

3 MR. HEYER: I mean, if there is a proffer that  
4 otherwise the principal of VPR is going to testify, I'll accept  
5 the proffer.

6 MR. ROTHMAN: All right. So we move those two into  
7 evidence, Your Honor.

8 THE COURT: So 26 and 27, any objection?

9 MR. HEYER: No objection, Your Honor.

10 THE COURT: Those exhibits are admitted without  
11 objection.

12 (Evidence admitted as Plaintiff's Exhibits 26 and 27)

13 BY MR. ROTHMAN:

14 Q You are not going to have to layoff employees if ELFBAR  
15 comes off the market, are you?

16 A Can you rephrase that.

17 Q The prior witness testified that, you know, if ELFBAR were  
18 removed from the market, he would have to layoff employees.

19 Would Demand Vape have to layoff employees if ELFBAR  
20 was removed from the market for a period of time?

21 A Potentially, yes. I mean, ELFBAR is very profitable for  
22 us. That's different than, you know, the total amount of sales  
23 that you do, so profit is what you make your money on, right.

24 Q How much more profitable is ELFBAR than other comparable  
25 products like the ones we saw on the first page of your

1 website?

2 A Each product varies.

3 Q Sure.

4 A Some drastically so.

5 Q Right. But how much more profitable is ELFBAR than, say,  
6 Flum or Biff Bar or Luffbar or Geek Bar?

7 A Well, quite a bit, because not only is it in high demand,  
8 but there is also a very good profit margin on it, probably the  
9 highest profit margin of any of those devices.

10 Q In your Exhibit 22, you indicated a 29 percent profit  
11 margin. How does that compare to the profit margin on Biff  
12 Bar?

13 A I don't have the exact number, but I think our average  
14 profit margin across our devices is around 15 percent.

15 Q 15 percent. So you are making double the profit on the  
16 ELFBAR than you are on these other products?

17 A Yeah, according to what I just said, that would be  
18 accurate, yes.

19 Q Okay. Is it really the fact that customers want the ELFBAR  
20 that's generating the demand as a result or is it really that  
21 the ELFBAR is so much more profitable, that you are selling  
22 that instead of alternative products?

23 A No. It's the first thing you said, because we make our  
24 products as well, and trust me, we would much rather sell those  
25 products than anything else, but people demand ELFBAR.

1 Q What is so appealing about that product?

2 A I wish I knew, I wish I could answer that question.

3 Q But you don't you know, though, because weren't you  
4 interviewed by Reuters and asked specifically about what it is  
5 that makes products like ELFBAR so in demand?

6 A Yeah, I gave them a very similar answer to what I just gave  
7 you.

8 Q Well, my understanding of the answer that you gave was that  
9 those products like ELFBAR that come in fruit and candy flavors  
10 are attractive to children, but despite the fact they are  
11 attractive to children, adults like them, too.

12 MR. HEYER: Objection, lack of foundation, hearsay.

13 THE COURT: All right, I'll sustain the objection.

14 BY MR. ROTHMAN:

15 Q Well, it's actually your statements, so --

16 THE COURT: I'm not really sure where this whole  
17 thing is going.

18 MR. ROTHMAN: I'll leave it. I'll leave it there,  
19 Your Honor. I appreciate that, I think we have probably  
20 covered all of the areas.

21 BY MR. ROTHMAN:

22 Q Weiboli is a Defendant in this case, Shenzhen Weiboli, or  
23 Weiboli Shenzhen, right?

24 A Correct.

25 Q They are not here, there is no representative of them here

1 today, right?

2 MR. HEYER: Objection, Your Honor, Counsel is here.

3 MR. ROTHMAN: Well, no, I'm asking in terms of a  
4 witness or a corporate representative. Obviously, Counsel is  
5 here, I see you there.

6 THE COURT: I think we can all understand that there  
7 is no physical human being here from --

8 BY MR. ROTHMAN:

9 Q Do you know why Shenzhen Weiboli is not here and presenting  
10 evidence about its losses?

11 A I can't --

12 MR. HEYER: Objection -- I'm sorry.

13 THE WITNESS: I can't speak for someone else, I have  
14 no idea why they aren't here.

15 BY MR. ROTHMAN:

16 Q Are you aware of other products sold under other brands by  
17 that company?

18 A Not to my knowledge, but in China, the business structures  
19 are set up in such a way where there is multiple facets to it,  
20 so I can't tell you definitively one way or another, I have no  
21 knowledge of that.

22 Q So the only brand that you are aware of that Shenzhen  
23 Weiboli sells and that you import into U.S. is the ELFBAR  
24 brand.

25 A As I sit here today, to my knowledge, yes.

1 Q Lost Mary is not the name of another brand that they make  
2 that you import?

3 A I'm not sure that is sold to us by Weiboli, I don't know,  
4 that's why I'm -- you know, there's different companies that we  
5 buy different things from.

6 Q Okay. But I was asking specifically about Shenzhen  
7 Weiboli, do you know if you buy the Lost Mary brand of  
8 disposable vape product from them?

9 A I don't know the answer to that question.

10 MR. ROTHMAN: Okay, thank you.

11 No further questions, Your Honor.

12 THE COURT: All right, thank you.

13 Any redirect?

14 MR. HEYER: Very briefly, your Honor.

15 REDIRECT EXAMINATION

16 BY MR. HEYER:

17 Q Mr. Glauser, were you present for Mr. Frija's testimony on  
18 November 18th during the first day of the preliminary  
19 injunction?

20 A Yes.

21 Q Do you recall his testimony to the effect -- I won't  
22 attempt to repeat his exact words, but to the effect that he  
23 attributed a decline in the ELF auto concealer sales in 2020  
24 and 2021 to the arrival of the ELFBAR products on the U.S.  
25 market?

1 product, right?

2 A Yes.

3 Q Above that is the Hyde product, correct?

4 A Correct.

5 Q Okay. To the left of the ELFBAR, what is that product?

6 A Flum probably; yes.

7 Q That product looks very similar to the ELFBAR product, is  
8 it a similar product, does it fall into the same category?

9 A Yes, it is a disposable device.

10 Q Okay. Below the Flum product, there is this product that  
11 looks very similar to the ELFBAR, I can't tell what that is by  
12 bar?

13 A I'm not sure where you are --

14 Q On the left-hand side of the screen, do you see the --

15 A Yep, Biff Bar.

16 Q And below the ELFBAR is the Luffbar.

17 A That's correct.

18 Q To the right of the Luffbar is the Geek Bar.

19 A Is that a question?

20 Q That's another product that's similar to the ELFBAR.

21 A Yes.

22 Q But I just want to make sure we understand each other, you  
23 want this Court to believe that despite the fact that your  
24 company distributes the Luffbar, the Biff Bar, the Geek Bar,  
25 the Flum Pebble, all of which are similar to the ELFBAR, that

1 enjoining the sales of the ELFBAR will lead to a vacuum where  
2 purchasers will end up buying counterfeit ELFBARs that will  
3 harm them, that's your testimony?

4 A That is correct, and I think that testimony is backed by  
5 history and a long pedigree in this industry.

6 Q And I understand you do have a long pedigree in this  
7 industry and I'm not challenging that, but you talked about  
8 surveys that you have done on e-cigarettes. Have those surveys  
9 been produced to us in this case?

10 MR. HEYER: Objection, Your Honor, discovery hasn't  
11 started.

12 THE COURT: All right, sustained.

13 MR. ROTHMAN: Okay.

14 BY MR. ROTHMAN:

15 Q I'm not aware of receiving any surveys that the Defendants  
16 are relying upon, okay. So are there any surveys that you  
17 intend to rely upon that I'm not aware of because you indicated  
18 that that was something that you were basing your testimony on?

19 MR. HEYER: Objection, Your Honor. We haven't even  
20 filed our answers to the complaint yet, this is an expedited  
21 preliminary injunction.

22 THE COURT: All right. Why don't -- I'll sustain the  
23 objection based on the way the question was presented.

24 But Mr. Rothman, if you want to ask the witness about  
25 surveys, you may do so. He did mention in his direct that his

1 company conducts surveys in a general sense, so you can probe  
2 that line of inquiry if you wish.

3 MR. ROTHMAN: Okay.

4 BY MR. ROTHMAN:

5 Q Is there a specific survey done by a specific survey  
6 company on a particular date concerning a particular product  
7 that you're relying upon here today?

8 A No.

9 Q You also referred to testing. Is there specific testing  
10 done on a specific product that you are relying on here today?

11 A Can you rephrase the question, because I'm not sure what  
12 you mean by relying on.

13 Q Well, I want to understand the basis for the position you  
14 are taking that removing ELFBAR is going to harm people, right,  
15 and you said you've done surveys, you have done testing, and  
16 you also referred to situations where there was an FDA hold  
17 placed on a product, it sounded like it was in customs, on an  
18 almost identical product type, and I want to understand what  
19 those specifics are if you are, in fact, asking the Court to  
20 rely upon them.

21 I'm not questioning your experience, I just want to  
22 know, sitting here today, is there something specific that you  
23 want the Court to refer to or is this just -- this is just your  
24 general experience?

25 A I appreciate you clarifying and let me clarify. I wasn't

1 relying on those things in a specific sense to prove that  
2 ELFBAR would be over -- would not get overtaken by something  
3 else.

4 I was relying on those things in a general sense, but  
5 my bigger reliance was on the historical data in sales I have  
6 on other products that were in a similar situation that is  
7 demonstratively proveable.

8 Q The historical data that you have indicates, and I'm  
9 quoting from your testimony on direct, that, quote, "Any time a  
10 demand is not met, someone fills that demand."

11 A That's correct.

12 Q Okay. So isn't it the case and perhaps just as likely that  
13 if the ELFBAR product is not available for purchase, that the  
14 demand for the product will be filled by another product like  
15 one of these other bar products we see on your website?

16 A No, I cannot agree with that statement at all. I don't  
17 think it's just as likely. I think it's much more likely that  
18 it will be filled by counterfeits.

19 Q Okay. And your basis for concluding that is what, other  
20 than this experience that you have told us about, what else?

21 A I gave specific examples such as Juul, Hyde, there are a  
22 couple other products in the past as well that faced similar  
23 situations and in every single one of those situations in the  
24 immediate aftermath -- yes, in time, they were replaced by  
25 other types of products, just as ELF did in this situation.

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2 it's not a negligible time period, it was fulfilled by  
3 counterfeits every single time, that's what I'm relying on.

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5 at the sales here in Exhibit 22, and I want to understand so  
6 that the Court can make a determination, how much time is it  
7 going to take for the demand for ELFBAR to be filled by other  
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9 counterfeit products; a month, two months, three months, how  
10 much time?

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15 absence of the ELFBAR product on the market could potentially  
16 lead people to be purchasing counterfeit product until it is  
17 filled by some other legitimate product seller, for lack of a  
18 better term than legitimate.

19 A That is one possible outcome, yes.

20 THE COURT: So when you refer to this prospect of  
21 purchasing counterfeit, what exactly are you referring to? So  
22 a counterfeit of the ELFBAR would be what exactly in your mind?

23 THE WITNESS: So Your Honor, a counterfeit, how I  
24 define it is something that looks exactly like Exhibit D19  
25 here, that has the same packaging, has the same markings, it

1 looks exactly like the product, but is not made by the original  
2 manufacturer, that's what I describe as a counterfeiter, Your  
3 Honor.

4 THE COURT: Then I have another question about the  
5 surveys, you mentioned them in your direct in relation to the  
6 potential for consumer confusion. Are you aware of any studies  
7 conducted by your company that have actually compared the  
8 prospect of confusion between ELFBAR and ELF products?

9 THE WITNESS: No, we have not done because as I  
10 stated in my previous testimony, I was not aware of the ELF  
11 product line until this lawsuit.

12 THE COURT: Understood, thank you.

13 BY MR. ROTHMAN:

14 Q Thanks. Now, you are aware of my client's company, though,  
15 right?

16 A Yes, as I previously stated, just from hearing of  
17 litigation in the industry.

18 Q But you also sell his products on your website, right?

19 A I'm not -- not that I'm aware of, I don't do the  
20 purchasing, so I don't know.

21 Q Okay. But my client has a few different -- you know my  
22 client has a few different brands it holds trademarks for,  
23 products under the name HoneyStick, are you familiar with that?

24 A No, I did not know your client held the trademark under the  
25 trademark HoneyStick until you just told me, so --

1 Q If we go and we look at your website for brands --

2 MR. ROTHMAN: Where did we see it?

3 (Discussion off the record.)

4 BY MR. ROTHMAN:

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6 HoneyStick products there that my client makes.

7 A Is that a question?

8 Q Well, I'm asking, now that you see that, do you agree that  
9 your company sells products that are made and distributed by  
10 VPR?

11 A To the extent that what you are telling me is accurate,  
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14 my client sells, these kit products, the ELF products.

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21 haven't held one previously, but the product that my client  
22 sells that is marked Plaintiff's Exhibit 26, does that fall  
23 into a category of products that we could find on the Demand  
24 Vape website?

25 A Can you be more specific with the question, what do you

1 mean by category?

2 Q Well, there are many different categories on the Demand  
3 Vape website and if we go to devices, there is a device  
4 category called kits, and if I click on kits, right, we see  
5 devices including -- see this Uwell device that Mr. Hardy (sic)  
6 was testifying about earlier today?

7 A I do.

8 Q Okay.

9 A I don't believe that's the same device though.

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11 Exhibit 16 or 17 to me, but these products we are looking at  
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13 these products are different from the ELFBAR product, what are  
14 the attributes of these products?

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16 you just handed me here --

17 Q Okay.

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19 to start vaping minus potentially whatever substance you are  
20 going to put into it.

21 (Evidence identified as Plaintiff's Exhibit No. 26.)

22 BY MR. ROTHMAN:

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24 client's ELF product that's been marked as Exhibit 26, that  
25 product is like the products that are listed on your website

1 under the devices kits subsection, correct?

2 A Yes, it's similar, correct.

3 Q Okay. And what about -- well, I'll show you what we will  
4 mark as Plaintiff's Exhibit 27.

5 MR. ROTHMAN: You don't have to get up, if you allow  
6 me to approach the witness.

7 MR. HEYER: Can we see what that is?

8 MR. ROTHMAN: It's the pen battery, it is the  
9 battery.

10 MR. HEYER: Thank you.

11 THE COURT: None of these exhibits yet have been  
12 admitted, correct, Mr. Rothman?

13 MR. ROTHMAN: They were shown before. If necessary,  
14 I can put them in through my client, if there is any objection.  
15 At this point, I'm just showing them to --

16 THE COURT: Okay.

17 MR. ROTHMAN: -- the witness for identification  
18 purposes.

19 THE COURT: Okay.

20 MR. ROTHMAN: Pictures of them have been admitted as  
21 exhibits already, though.

22 THE COURT: Okay.

23 BY MR. ROTHMAN:

24 Q What category would that exhibit fall into, that product,  
25 the device you are holding?

1 A This is a battery.

2 (Evidence identified as Plaintiff's Exhibit No. 27.)

3 BY MR. ROTHMAN:

4 Q Okay. Would you attach something to the battery?

5 A You could, yes.

6 Q Okay. And would that something that you attached to the  
7 battery be a vaporizer that you could put liquid into?

8 A Potentially, yes. There is a -- there is what you call a  
9 510 connection to it, which is the industry standard. So you  
10 can connect almost anything you wanted to this battery that has  
11 a 510 threaded adapter on it.

12 Q Okay. So that 510 threaded adapter could be filled with  
13 nicotine e-liquid, and then it would function like any of the  
14 devices that we saw on the kits site when they were filled,  
15 right?

16 A It would function in a similar manner, yes, it would become  
17 essentially a kit. But this, in and of itself, wouldn't be  
18 considered a kit.

19 Q That's just the battery part you need to attach the  
20 reservoir for the e-liquid to what you refer to as the 510  
21 mouthpiece, correct?

22 A Correct, yes.

23 Q Do you sell those 510 mouthpieces on Demand Vape?

24 A Yeah, I'm sure we do. We sell a ton of different -- you  
25 know, across all categories.

1 MR. ROTHMAN: Is there any objection to the admission  
2 of Exhibits 26 and 27?

3 MR. HEYER: I mean, if there is a proffer that  
4 otherwise the principal of VPR is going to testify, I'll accept  
5 the proffer.

6 MR. ROTHMAN: All right. So we move those two into  
7 evidence, Your Honor.

8 THE COURT: So 26 and 27, any objection?

9 MR. HEYER: No objection, Your Honor.

10 THE COURT: Those exhibits are admitted without  
11 objection.

12 (Evidence admitted as Plaintiff's Exhibits 26 and 27)

13 BY MR. ROTHMAN:

14 Q You are not going to have to layoff employees if ELFBAR  
15 comes off the market, are you?

16 A Can you rephrase that.

17 Q The prior witness testified that, you know, if ELFBAR were  
18 removed from the market, he would have to layoff employees.

19 Would Demand Vape have to layoff employees if ELFBAR  
20 was removed from the market for a period of time?

21 A Potentially, yes. I mean, ELFBAR is very profitable for  
22 us. That's different than, you know, the total amount of sales  
23 that you do, so profit is what you make your money on, right.

24 Q How much more profitable is ELFBAR than other comparable  
25 products like the ones we saw on the first page of your

1 website?

2 A Each product varies.

3 Q Sure.

4 A Some drastically so.

5 Q Right. But how much more profitable is ELFBAR than, say,  
6 Flum or Biff Bar or Luffbar or Geek Bar?

7 A Well, quite a bit, because not only is it in high demand,  
8 but there is also a very good profit margin on it, probably the  
9 highest profit margin of any of those devices.

10 Q In your Exhibit 22, you indicated a 29 percent profit  
11 margin. How does that compare to the profit margin on Biff  
12 Bar?

13 A I don't have the exact number, but I think our average  
14 profit margin across our devices is around 15 percent.

15 Q 15 percent. So you are making double the profit on the  
16 ELFBAR than you are on these other products?

17 A Yeah, according to what I just said, that would be  
18 accurate, yes.

19 Q Okay. Is it really the fact that customers want the ELFBAR  
20 that's generating the demand as a result or is it really that  
21 the ELFBAR is so much more profitable, that you are selling  
22 that instead of alternative products?

23 A No. It's the first thing you said, because we make our  
24 products as well, and trust me, we would much rather sell those  
25 products than anything else, but people demand ELFBAR.

1 Q What is so appealing about that product?

2 A I wish I knew, I wish I could answer that question.

3 Q But you don't you know, though, because weren't you  
4 interviewed by Reuters and asked specifically about what it is  
5 that makes products like ELFBAR so in demand?

6 A Yeah, I gave them a very similar answer to what I just gave  
7 you.

8 Q Well, my understanding of the answer that you gave was that  
9 those products like ELFBAR that come in fruit and candy flavors  
10 are attractive to children, but despite the fact they are  
11 attractive to children, adults like them, too.

12 MR. HEYER: Objection, lack of foundation, hearsay.

13 THE COURT: All right, I'll sustain the objection.

14 BY MR. ROTHMAN:

15 Q Well, it's actually your statements, so --

16 THE COURT: I'm not really sure where this whole  
17 thing is going.

18 MR. ROTHMAN: I'll leave it. I'll leave it there,  
19 Your Honor. I appreciate that, I think we have probably  
20 covered all of the areas.

21 BY MR. ROTHMAN:

22 Q Weiboli is a Defendant in this case, Shenzhen Weiboli, or  
23 Weiboli Shenzhen, right?

24 A Correct.

25 Q They are not here, there is no representative of them here

1 today, right?

2 MR. HEYER: Objection, Your Honor, Counsel is here.

3 MR. ROTHMAN: Well, no, I'm asking in terms of a  
4 witness or a corporate representative. Obviously, Counsel is  
5 here, I see you there.

6 THE COURT: I think we can all understand that there  
7 is no physical human being here from --

8 BY MR. ROTHMAN:

9 Q Do you know why Shenzhen Weiboli is not here and presenting  
10 evidence about its losses?

11 A I can't --

12 MR. HEYER: Objection -- I'm sorry.

13 THE WITNESS: I can't speak for someone else, I have  
14 no idea why they aren't here.

15 BY MR. ROTHMAN:

16 Q Are you aware of other products sold under other brands by  
17 that company?

18 A Not to my knowledge, but in China, the business structures  
19 are set up in such a way where there is multiple facets to it,  
20 so I can't tell you definitively one way or another, I have no  
21 knowledge of that.

22 Q So the only brand that you are aware of that Shenzhen  
23 Weiboli sells and that you import into U.S. is the ELFBAR  
24 brand.

25 A As I sit here today, to my knowledge, yes.

1 Q Lost Mary is not the name of another brand that they make  
2 that you import?

3 A I'm not sure that is sold to us by Weiboli, I don't know,  
4 that's why I'm -- you know, there's different companies that we  
5 buy different things from.

6 Q Okay. But I was asking specifically about Shenzhen  
7 Weiboli, do you know if you buy the Lost Mary brand of  
8 disposable vape product from them?

9 A I don't know the answer to that question.

10 MR. ROTHMAN: Okay, thank you.

11 No further questions, Your Honor.

12 THE COURT: All right, thank you.

13 Any redirect?

14 MR. HEYER: Very briefly, your Honor.

15 REDIRECT EXAMINATION

16 BY MR. HEYER:

17 Q Mr. Glauser, were you present for Mr. Frija's testimony on  
18 November 18th during the first day of the preliminary  
19 injunction?

20 A Yes.

21 Q Do you recall his testimony to the effect -- I won't  
22 attempt to repeat his exact words, but to the effect that he  
23 attributed a decline in the ELF auto concealer sales in 2020  
24 and 2021 to the arrival of the ELFBAR products on the U.S.  
25 market?

1 A I am, yes.

2 Q Okay. And is that possible based on your experience and  
3 knowledge about your company's sales of ELFBAR products?

4 MR. ROTHMAN: Your Honor, objection. This goes  
5 beyond the scope of both direct and cross.

6 THE COURT: Overruled.

7 THE WITNESS: No, I don't believe that's possible  
8 based on my experience in the industry. I mean, there was a  
9 full two-year period where they could have established their  
10 product, that's more than the lifespan of most products that  
11 become successful.

12 BY MR. HEYER:

13 Q Was Demand Vape selling any ELFBAR products in 2020?

14 A No.

15 Q And when, looking at Exhibit 22, did Demand Vape start  
16 selling in 2021?

17 A Approximately October 2021.

18 MR. HEYER: Thank you, Your Honor. No further  
19 questions.

20 THE COURT: Thank you, Mr. Glauser.

21 THE WITNESS: Thank you, Your Honor.

22 (Witness excused)

23 THE COURT: All right, Mr. Heyer, do you have any  
24 additional witnesses to present today?

25 MR. HEYER: We do not, Your Honor.

# **EXHIBIT G**

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
WEST PALM BEACH DIVISION

VPR BRANDS, LP,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 9:22-cv-81576
	)	
SHENZHEN WEIBOLI TECHNOLOGY	)	
CO., LTD., et al.	)	
	)	
Defendants.	)	
_____	)	

**DEFENDANTS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

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Defendants Shenzhen Weiboli Technology Co., Ltd. (“Weiboli”), YLSN Distribution LLC, ECTO World LLC, Safa Goods LLC, D&A Distribution LLC, Unishow (U.S.A.), Inc.,<sup>1</sup> SV3 LLC, and Kingdom Vapor, Inc. (collectively, “Defendants”), pursuant to the Court’s December 5, 2022 order [ECF No. 53], submit these proposed findings of fact and conclusions of law:

### **PROPOSED FINDINGS OF FACT**

#### **I. BACKGROUND FACTS ON PARTIES AND MARKS**

##### **A. VPR and the ELF Mark and Products**

1. VPR Brands, LP (“VPR”) is a publicly traded company that develops and markets vaporizers and products in the electronic cigarette industry. (D-8, -15 [ECF 58-8, -13]; Frija Hearing Transcript of November 18, 2022 (“T-1”) 17:7-18:2 [ECF 46].)

2. In November 2017, VPR placed its initial purchase order with a Chinese manufacturer for, and began marketing, electronic cigarette products under the “ELF” brand. (Frija T-1 19:2-9; 30:24-31:4, PX-9 [ECF 38-9].)

3. VPR did not apply to the Food and Drug Administration (“FDA”) for or obtain marketing authorization for any of its ELF-branded electronic cigarettes before selling them in the United States. (Frija T-1 91:6-13; D-1 [ECF 58-1].)

4. VPR markets two electronic cigarette products under the ELF mark, the auto draw ELF conceal kit, which is a box-shaped vaporizer with a mouthpiece attached, and a pen-shaped battery (Frija T-1 19:6-9; 20:7-12; 21:9-16; PX-2 -4, -27 [ECF 38-2, -4; ECF 54-6].)

5. The square or box or “bar” shape of VPR’s ELF-branded electronic cigarette is not unique, as the shape is widely used in the electronic cigarette industry and VPR does not possess any proprietary rights in that shape. (Frija T-1 57:4; 96:21-98:20; 118:20-23.)

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<sup>1</sup> Unishow joins in this submission although it has yet to be served with the summons and complaint and plans to move to dismiss based on lack personal jurisdiction once served. All other Defendants also plan to file an omnibus motion to dismiss VPR’s Complaint.

6. A “vaporizer” is a device with a battery and a heating element that allows the user to inhale essential oils, supplements, cannabis, nicotine, and other products. (Frija T-1 18:3-13.)

7. VPR’s “ELF” vaporizer is a rechargeable and reusable product that is sold without any inhalable substance inside (i.e., empty). (Frija T-1 20:16-21; 25:16-22.)

8. VPR’s “ELF” pen-shaped battery is intended to be used with what is known in the electronic cigarette industry as a 510 cartridge, an older generation of electronic cigarette products that are not currently popular with consumers. (Frija T-1 107:1-108:11.)

9. VPR’s ELF vaporizers are not explicitly marketed for use with nicotine-containing liquids, but Kevin Frija, VPR’s president, testified that he expects that consumers use VPR’s ELF products with nicotine. (Frija T-1 72:15-20; D-15.)

10. In June 2018, VPR registered the “ELF” trademark under International Class 34 for electronic cigarette lighters, electronic cigarettes, and smokeless cigarette vaporizer pipe. (PX-1 [ECF 38-1].)

11. The “ELF” mark is typically enclosed within a circle on packaging and devices. (D-14 [ECF 58-12].)

## **B. Defendants and the ELFBAR Mark and Products**

### *1. Defendant Shenzhen Weiboli*

12. VPR claims that Defendant Shenzhen Weiboli sells electronic cigarettes under the “ELFBAR” brand and mark to distributors in the United States.

13. Weiboli has registered the “ELFBAR” trademark internationally, including in Europe, Asia, and the Middle East, with more applications still pending. (D-7 [ECF 58-7].)

14. In July 2021, the United States Patent and Trademark Office (USPTO) issued an Office Action rejecting Shenzhen Weiboli’s application to register “ELFBAR.” (PX-3 [ECF 38-3].)

15. In advertising and packaging, the “ELFBAR” mark is near or next to a distinct bubble and leaves mark or logo. (PX-15, -17, -18 -20 [ECF 38-14, -16, -17, -19]; D-19 [ECF 58-17].)

16. The ELFBAR electronic cigarette is a bar-shaped device that, unlike the ELF-branded electronic cigarette, is sold pre-filled with nicotine-containing liquid and is disposed of once the liquid is depleted. It is known as a “disposable” electronic cigarette. (Frija T-1 34:14-19; Shriteh Hearing Transcript of December 8, 2022 (“T-2”) 63:20-64:12 [ECF 60].)

17. Defendants YLSN Distribution LLC, ECTO World LLC, Safa Goods LLC, D&A Distribution LLC, Unishow (U.S.A.), Inc., SV3 LLC, and Kingdom Vapor, Inc. are master distributors of ELFBAR products in the United States.

2. *Defendant Ecto World LLC a/k/a Demand Vape*

18. Ecto World LLC, also known as Demand Vape, distributes electronic cigarettes nationwide and internationally, employing about 283 people. (Glauser T-2 85:8-23.)

19. Jon Glauser, Demand Vape’s founder, has worked in the electronic cigarette industry for approximately 13 years, and founded Demand Vape in 2011. (Glauser T-2 86:1-11.)

20. Demand Vape is one of the largest electronic cigarette distributors in the United States, offering about 30,000 products and selling to approximately 5,000 retailers in 49 states. (Glauser T-2 86:20-87:12.)

21. Before this lawsuit, Demand Vape was unaware of any ELF-branded electronic cigarettes. (Glauser T-2 87:2-89; 113:4-11.)

3. *Defendant Safa Goods, LLC*

22. Safa Goods, founded in 2018, is located in Port Charlotte, Florida. (Shriteh T-2 55:1-10.)

23. Safa Goods’ operations manager, Haitham Shriteh, started in the electronic cigarette industry in approximately 2016 and worked for other wholesale companies and operated retail shops before owning Safa Goods. (Shriteh T-2 55:14-22.)

24. Safa Goods sells over 1,000 different electronic cigarette products across about 50 brands and serves as a master distributor and distributor of electronic cigarette products. (Shriteh T-2 56:2-20; 61:9-11.)

25. Before this lawsuit, Shriteh and Safa Goods had never heard of the ELF brand, despite being based in Florida like VPR. (Shriteh T-2 56:25-57:10.)

## **II. FDA’S E-CIGARETTE REGULATIONS APPLY TO VPR’S ELF PRODUCTS**

26. The Federal Food, Drug, and Cosmetic Act (“FDCA”) requires FDA marketing authorization for any new tobacco product sold in the United States. (Haynes T-2 18:1-13.)

27. In 2016, FDA adopted the “Deeming Rule,” 21 C.F.R. § 1143.1, which deemed electronic cigarettes as subject to the FDCA and FDA’s authority. (Haynes T-2 19:17-20:8; 52:6-10.)

28. The definition of a “tobacco product” in FDA’s regulations includes components and accessories that do not contain nicotine if the product or device is intended or reasonably expected to be used with the consumption of a tobacco product or to affect a tobacco product’s performance or characteristics. (Haynes T-2 28:14-29:13.)

29. Open-system electronic cigarette products and batteries like VPR’s ELF-branded electronic cigarettes are subject to the FDCA and FDA’s jurisdiction and requirements as “tobacco products” so long as they are intended or expected to be used with tobacco or nicotine. (*Id.*; Haynes T-2 21:1-10; 38:6-39:11; 21 C.F.R. § 1140.3.)

30. FDA adopted a broad definition of “tobacco product” to include products reasonably expected to be used with nicotine so that open-system electronic cigarette products like VPR’s ELF-branded products could not avoid regulation. (Haynes T-2 19:18-24.)

31. When the Deeming Rule was promulgated, FDA also adopted a deferred enforcement policy for electronic cigarettes so that if a product was on the United States market by the effective

date of the Deeming Rule, August 8, 2016, it could stay on the market so long as the supplier sought a marketing authorization from FDA by a specified date. (Haynes T-2 22:12-23:5.)

32. The deadline for filing an application for a marketing authorization from FDA, a Premarket Tobacco Product Application, was originally set for August 2018, but was later moved to September 9, 2020. (Haynes T-2 23:2-18; D-4 [ECF 58-4].)

33. FDA requires a marketing authorization order for electronic cigarettes components even if they are sold without any liquid or other nicotine-containing substance, and batteries sold alone are specifically mentioned in the Deeming Rule. (Haynes T-2 28:14-24.)

34. If an electronic cigarette, including an open-system device or battery, subject to the Deeming Rule came on the market after August 8, 2016, it was required to obtain marketing authorization from FDA prior to being sold. (Haynes T-2 28:4-11)

35. In early 2020, FDA issued Guidance stating it was subjecting cartridge- or pod-based electronic cigarette products that came in flavors other than tobacco and menthol to immediate enforcement, requiring them to come off the market. (Haynes 26:23-27:14; D-2, -3 [ECF 58-2, -3].)

36. Disposable electronic cigarette products were excluded from this enforcement policy, so they remained subject to the existing deferred enforcement policy. (Haynes 27:17-24; D-2.)

37. FDA has taken enforcement action against open-system electronic cigarettes that, like VPR's ELF-branded electronic cigarettes, do not contain nicotine, including in the form of warning letters. (Haynes T-2 20:9-15; 29:15-30:3; 32:3-38:5; D-5, -6, -16-18 [ECF 58-5, -6, -14-16].)

38. Warning Letters are an enforcement activity and a common way for FDA to signal that there is an issue with a company's conduct or product, and that the product appears to be an unauthorized new tobacco product. (Haynes T-2 17:16-18; 38:2-5; D-5.)

39. A warning letter also is an indicator that a particular product or type of product is considered a regulated tobacco product. (Haynes T-2 20:22-23; D-5.)

40. Since VPR's ELF-branded electronic cigarettes are intended for or reasonably expected to be used with the consumption of a tobacco product, they fall within the definition of "tobacco product" and are subject to the FDCA and FDA regulation. (Haynes T-2 38:6-21.)

41. Because VPR's ELF-branded electronic cigarettes were not sold in the United States until 2017, after the August 8, 2016 effective date of the Deeming Rule, they required a marketing authorization order from FDA before they could be sold and are not subject to the FDA's deferred enforcement policy. (Haynes T-2 39:15-23.)

42. VPR has not applied for or obtained a marketing authorization order for either of its ELF-branded products. (Frija T-1 91:6-13; D-1.)

43. VPR's ELF-branded electronic cigarette products are adulterated and unlawfully marketed in violation of the FDCA because they are not subject to FDA's deferred enforcement policy and VPR did not obtain marketing authorization before their sale in the United States, nor does VPR currently have a marketing application pending with the FDA. (Haynes T-2 40:24-41:7.)

### **III. THE BROADER ELECTRONIC CIGARETTE INDUSTRY AND MARKET**

44. The electronic cigarette industry is largely made up of either open-system or closed-system devices. An open system does not contain any nicotine or liquid and allows the consumer to choose what they want to put in the device. A closed system contains a consumable, like a nicotine liquid, or is designed for use with a cartridge containing the consumable that a supplier sells. (Haynes T-2 25:20-26:5.)

45. A product is generally only referred to as an "electronic cigarette" if at least one of its intended uses is for use with tobacco or nicotine. (Haynes T-2 38:25-39:6; D-15.)

46. Open-system electronic cigarettes are more technical for consumers to use and closed-system electronic cigarettes are an easier “on-the-go” product with less maintenance and are more convenient to use. (Shriteh T-2 63:20-64:6.)

47. The experience of using a disposable like ELFBAR versus a refillable system like the ELF-branded product is like “night and day.” (Glauser T-2 94:2-12.)

48. The convenience of using a disposable makes it more accessible to users and is a primary driver of the popularity of disposables like ELFBAR over open-system electronic cigarettes like the ELF-branded products. (Glauser T-2 95:4-12.)

49. In the past, open-system or cartridge-based electronic cigarettes were more popular, but now disposables like ELFBAR are the most popular type of electronic cigarettes on the market. (Glauser T-2 93:3-95:12.)

#### **IV. VPR’S SALES AND MARKET PRESENCE**

50. VPR began marketing ELF-branded products in 2017 and selling ELF-branded products in 2018. (Frija, T-1, 30:24-31:4, PX-10 [ECF 38-10].)

51. Approximately 90 percent of VPR’s sales are at wholesale, with some retail sales made through its Honeystick website. (Frija T-1, 24:6-9; 117:7-9; D-14.)

52. No Defendant uses VPR’s Honeystick website to sell ELFBAR products. *Id.*

53. VPR testified that its ELF-brand products are sold in smoke shops, vape shops, gas stations, convenience stores, and some supermarkets, but did not provide any testimony or documentary evidence, such as detailed sales records, to support the testimony. (Frija T-1, 24:10-15; Frija T-2 125:25-126:2.)

54. Although they regularly visit retail outlets that sell electronic cigarette products, Defendants’ principals have never encountered VPR’s ELF-branded products or seen any signage or advertising for the products. (Shriteh T-2 60:24-62:9; Glauser T-2 87:2-89:9; 90:16-91:19.)

55. VPR markets ELF-brand products not only to nicotine users but also to recreational, non-addicted users of alternative or non-nicotine products, such as THC, CBD, and similar substances. (Glauser 92:14-93:2.; D-15)

56. VPR's enterprise-wide annual revenues only fall in the \$5,000,000 range. (Frija T-1, 113:5-17; D-8-10 [ECF 58-8-10.]

57. VPR's readily admits that sales of ELF-branded products have been "paltry." (Frija T-2 126:8-16.)

58. VPR has sold only approximately 475,000 units branded as ELF in the United States since 2018. (Frija T-1, 30:24-31:9; 121:5-8; PX-10.)

59. VPR's sales of ELF-branded products were approximately \$1 million in 2018 and 2019, and declined substantially from there, averaging only about half a million dollars per year over almost five years. (Frija, T-1 106:13-22.)

60. VPR's gross sales for ELF-branded products between January 2018 and August 2022 was \$2,464,378.85, resulting in profits of approximately \$1 million. (Frija, T-1, 33:25.)

61. VPR's sales of ELF-branded products declined precipitously since its launch in early-2018, and that decline started well before Defendants' ELFBAR products entered and gained prominence in the U.S. market. (Frija 30:24-31:9; Shriteh 57:11-18; Glauser 88: 10-17.)

62. VPR's ELF-branded products' sales dropped in 2020 and continued to slow down considerably in 2021 and 2022. (Frija, T-1, 30:24-31:4.)

63. VPR produced a digital image of point-of-sale advertisement that retailers could purchase, but no evidence of any retailers actually purchasing the advertisement. (PX-6 [ECF 38-6].)

64. VPR acknowledged that its ELF products are not displayed "in a prominent space" in stores. (Frija T-2 126:22-25.)

65. VPR produced a digital image of an advertisement it claimed was used in business-to-business trade magazines, but no evidence on when or how often the advertisement ran in any magazine. (PX-5 [ECF 38-5].)

66. Defendants' witnesses testified that despite regularly attending electronic cigarette industry trade shows they never encountered or saw advertising or other signs of VPR or its ELF brand. (Shriteh T-2 60:19-23; 62:5-9; Glauser T-2 90:11-91:11.)

67. Similarly, while Defendants receive industry trade magazines, they never encountered or saw advertising for VPR or its ELF brand. (Shriteh T-2 76:24-77:4.)

68. VPR provided no evidence of advertising expenditures, including for its ELF products.

## **V. DEFENDANTS' ELFBAR SALES AND MARKET PRESENCE**

69. VPR had approximately two to three years to establish its ELF-branded products before ELFBAR gained prominence, longer than the lifespan of most products that become successful, as electronic cigarette consumer tastes change "almost yearly." (Frija T-1 108:9-10; Glauser T-2 122:21-123:11.)

70. VPR first learned of ELFBAR being advertised and sold in the United States in May 2022, several months after Defendants began selling the product. (Frija T-1 34:11-19.)

71. Demand Vape began distributing ELFBAR brand electronic cigarettes around October 2021, and ELFBAR increased substantially in popularity in the spring of 2022, with sales continuing to grow over the year as it has become the number one electronic cigarette product in the United States. (Glauser T-2 88:10-21.)

72. Demand Vape's sales of ELFBAR-branded products have continued to increase over the last year and have resulted in over \$38 million in profits for Demand Vape. (D-22 [ECF 58-19].)

73. ELFBAR sales account for 25 to 35 percent of Demand Vape's revenues and about one third of its overall profits because it is one of the most popular products and has one of the highest

profit margins of any similar electronic cigarette device. (Glauser T-2 89:4-8; 97:8-13, 17-19; 101:4-12; 119:5-18; D-22.)

74. Forcing Demand Vape to stop selling ELFBAR electronic cigarettes would be detrimental, as ELFBAR sales make up about one-third of the Company's profits and without it, Demand Vape would have to lay off as many as 100 employees. (Glauser T-2 101:4-12.)

75. Safa Goods began selling ELFBAR in January 2022. (Shriteh T-2 57:11-18.)

76. During the spring of 2022, ELFBAR started to become popular, and, in Mr. Shriteh's view ELFBAR is the most popular product in the disposable or closed-system e-cigarette category. According to Mr. Shirteh, ELFBAR is the most popular electronic cigarette in the State of Florida. (Shriteh T-2 57:19-59:10.)

77. Safa Goods' sales of ELFBAR products have continued to increase in 2022 and resulted in over \$100 million in revenue, and over \$11 million in profit for the company. (D-21 [ECF 58-18].)

78. Safa Goods' sales of ELFBAR have grown rapidly over the course of 2022, accounting for over 50 percent of Safa Goods' business. (Shriteh T-2 59:13-16, 60:14-18; D-21.)

79. Safa Goods currently employs over 40 people, 19 of whom Safa Goods hired to keep up with the high demand for ELFBAR. (Shriteh T-2 55:6-8, 59:17-25.)

80. If Safa Goods is forced to stop selling ELFBAR products, it would affect more than 50 percent of Safa Goods' revenue and require employee layoffs. (Shriteh T-2 72:3-7.)

81. Defendants' customers and the targets for ELFBAR-branded electronic cigarettes are generally nicotine-addicted adults who want to transition to a safer alternative to combustible cigarettes. (Glauser T-2 92:14-93:2.)

82. Jon Glauser, the owner of Demand Vape, has never heard ELFBAR-branded electronic cigarettes referred to by anyone in the industry as "ELF." (Glauser T-2 90:7-10.)

83. VPR presented no evidence that demonstrated an instance of actual confusion.

84. VPR submitted a single text message from a former distributor, but it did not impact any sales decisions and so did not evidence consumer confusion. (Frija T-1 98:23-99:17; PX-11 [ECF 38-11].)

85. No customers have ever indicated to Defendant Safa Goods that they are confused by or between ELF and ELFBAR. (Shriteh T-2 63:12-17.)

86. No customers have ever inquired to Demand Vape or its 32 sales representatives about any confusion between ELF and ELFBAR. (Glauser T-2 91:12-92:3.)

87. When distributors like Safa Goods and Demand Vape have struggled to meet high consumer demand for ELFBAR due to low supply, counterfeit ELFBAR products have entered the U.S. market. (Shriteh T-2 70:16-71:18; 72:8-13; Glauser T-2 99:18-100:1; D-21.)

88. Counterfeit electronic cigarettes often look exactly like the original electronic cigarette with the same or nearly identical packaging, except they are not made by the same manufacturer. (Glauser T-2 112:20-113:3.)

89. A similar counterfeit problem occurred when other popular electronic cigarette brands were pulled from the market or cannot satisfy consumer demand. (Glauser T-2 100:2-8; 108:22-109:5.)

90. If ELFBAR is removed from the market, counterfeit products are most likely to fill the void left as some distributors are likely to be fooled by counterfeits as has happened with similar products in the past. (Shriteh T-2 75:13-17; Glauser T-2 111:4-112:3.)

91. Even if a legitimate product could fill the ELFBAR void, it will likely take 40 to 90 days. (Glauser T-2 112:4-19.)

92. These counterfeit products lack the same quality control as legitimate or authentic electronic cigarette products as they often come from disreputable manufacturers and are made at

a very low quality, potentially exposing users to dangerous levels of toxins or chemicals, such as heavy metals, and putting consumers' health at risk. (Shriteh T-2 72:14-20; Glauser T-2 98:18-23; 99:11-17; 102:25-103:1.)

## **CONCLUSIONS OF LAW**

### **I. PRELIMINARY INJUNCTION STANDARD**

For the Court to grant a preliminary injunction, Plaintiff must establish: (1) a substantial likelihood of success on the merits of the underlying case (2) the movant will suffer irreparable harm in the absence of an injunction; (3) the harm suffered by the movant in the absence of an injunction would exceed the harm suffered by the opposing party if the injunction issued; and (4) an injunction would not disserve the public interest. *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1246-47 (11th Cir. 2002). "A preliminary injunction is an extraordinary and drastic remedy not to be granted unless the movant clearly established the 'burden of persuasion' as to all four elements." *Davidoff & Cie, S.A. v. PLD Int'l Corp.*, 263 F.3d 1297, 1300 (11th Cir. 2001) (quoting *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000 (en banc))).

### **II. VPR HAS NOT SHOWN IT IS SUBSTANTIALLY LIKELY TO SUCCEED ON THE MERITS**

VPR has not proven that it is substantially likely to succeed on the merits of its claims of trademark infringement under the Lanham Act, 15 U.S.C. § 1114, and therefore does not have a substantial likelihood of success on its other claims. To prove trademark infringement, a plaintiff must prove: (1) ownership of a trademark that has priority, is valid, and is protectable; and (2) that the defendant's mark is likely to cause consumer confusion. *Tana v. Dantanna's*, 611 F.3d 767, 773 (11th Cir. 2010). VPR has not shown a substantial likelihood of success on either prong.

First, VPR has been illegally marketing and selling its ELF electronic cigarette products in violation of the FDCA, and thus cannot establish lawful use of the ELF mark in commerce.

Although the Eleventh Circuit has yet to adopt the “unlawful use” defense, it has not rejected the defense, and this District has recognized the defense. *See FN Herstal SA v. Clyde Armory, Inc.*, 838 F.3d 1071, 1086-87 (11th Cir. 2016) (“This Court has not adopted the unlawful use doctrine and need not do so today because even if we were to adopt it, [plaintiff] has not submitted evidence sufficient to raise an issue of fact in this respect.”); *Plant Food Sys. v. AgroSource, Inc.*, 2016 U.S. Dist. LEXIS 124185, at \*57 (S.D. Fla. Sept. 12, 2016) (recommending denial of motion for preliminary injunction in part because plaintiff’s fertilizer product labels contained language similar to language EPA had found to make improper pesticidal claims); *Craft Kratom Lab, Inc. v. Mancini*, 2013 U.S. Dist. LEXIS 105852 (S.D. Fla. July 29, 2013).

Second, even if VPR could establish lawful use, analysis of the relevant factors shows that VPR cannot prove a substantial likelihood of confusion—the touchstone of its trademark claims.

In light of the facts and substantial question surrounding whether VPR engaged in lawful use of its mark in commerce and the likelihood of confusion, VPR has not established a substantial likelihood of prevailing on the merits of its trademark infringement claims.

#### **A. VPR’s Asserted Trademark is Unenforceable Due to Illegality**

Ownership of a legally protectable trademark requires *lawful* use of the trademark in commerce. *See CreAgri, Inc. v. USANA Health Sciences, Inc.*, 474 F.3d 626, 630 (9th Cir. 2007) (“It has long been the policy of the PTO’s Trademark Trial and Appeal Board that use in commerce only creates trademark rights when the use is lawful . . . [W]e also . . . hold that only lawful use in commerce can give rise to trademark priority.”); *United Phosphorus, Ltd. v. Midland Fumigant, Inc.*, 205 F.3d 1219, 1225 (10th Cir. 2000) (observing that “shipping goods in violation of federal law cannot qualify as the ‘use in commerce’ necessary to establish trademark rights” and suggesting that had the plaintiff sold its fumigant product without registering with the EPA, the defendant would have had a strong case that the plaintiff did not have a right in the trademark);

*Gray v. Daffy Dan's Bargaintown*, 823 F.2d 522, 526 (Fed. Cir. 1987) (“A valid application cannot be filed at all for registration of a mark without “lawful use in commerce.”); *AOP Ventures, Inc. v. Steam Distrib., LLC*, No. CV-15-1586, 2016 U.S. Dist. LEXIS 193035, at \*14-15 (C.D. Cal. Oct. 11, 2016); *Dessert Beauty, Inc. v. Fox*, 617 F. Supp. 3d 185, 190 (S.D.N.Y. 2007); *see also Plant Food Sys.*, 2016 U.S. Dist. LEXIS 124185, at \*57.<sup>2</sup>

A *per se* violation of a statute regulating the sale of a party's goods constitutes sufficient grounds for finding unlawful use. *Dessert Beauty*, 617 F. Supp. 3d at 190. Any tobacco product, including electronic cigarettes, introduced into U.S. commerce after February 15, 2007 requires an FDA marketing authorization order. 21 U.S.C. § 387(a). Any product lacking such a marketing authorization is “adulterated,” 21 U.S.C. § 387b(6)(A), and the “introduction or delivery into interstate commerce of any . . . tobacco product that is adulterated” is prohibited. 21 U.S.C. § 331(a). FDA's deferred enforcement policy allowed electronic cigarettes commercially marketed before August 8, 2016, to remain on the market while their timely filed premarket applications were pending.

VPR admits that it began marketing its electronic cigarettes and electronic cigarette accessories bearing the ELF mark in November 2017, and that it has not received a marketing authorization order, or even applied for such authorization from the FDA. Even allowing for

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<sup>2</sup> At the hearing, VPR's counsel cited two cases, *In re Fontem*, 2016 U.S. Dist. LEXIS 200633, 2016 WL 11503066 (C.D. Cal. Apr. 22, 2016), and *In re: JUUL*, 497 F. Supp. 3d 552 (N.D. Cal. Oct. 23, 2020), in arguing against application of the unlawful use doctrine, but neither case deals with the unlawful use issue or the legality of VPR's products. Instead, those cases dealt with the question of preemption, and whether federal regulation of electronic cigarettes preempted certain state law claims or assigned primary jurisdiction to the FDA on certain matters or questions of law. In the case of *In re Fontem*, the decision cited came before the Deeming Rule and FDA's deferred enforcement policy went into effect.

FDA's deferred enforcement policy, VPR's marketing of its ELF-branded electronic cigarettes is a *per se* violation of 21 U.S.C. § 331(a).

Expert testimony proffered by Defendants confirms that "open-system" electronic cigarette products such as VPR's ELF-branded products are "tobacco products" subject to the FDCA and FDA's authority, as they are "intended or reasonably expected" to be used with the consumption of a tobacco product. *See* 21 C.F.R. § 1140.3; *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019). The purpose of this broader definition of "tobacco product" was to ensure that products like VPR's ELF-branded e-cigarettes could not skirt regulation and FDA oversight.

The applicability of the FDCA's marketing authorization requirements to "open-system" electronic cigarette products like VPR's ELF-branded products reasonably expected to be used with nicotine is also demonstrated by FDA's previous enforcement actions against similar "open-system" electronic cigarette products.

The Court finds Defendants' evidence persuasive and its expert's opinions credible that VPR's ELF-branded electronic cigarettes are not lawfully marketed under the FDCA because they are a new tobacco product introduced in 2017 for which VPR has not obtained marketing authorization from FDA. Because the marketing and sale of VPR's ELF-branded electronic cigarettes is a *per se* violation of the FDCA, VPR has no lawful trademark rights in the ELF mark.

Further, even if the Court did not adopt or apply the "unlawful use" doctrine now, the evidentiary record creates a substantial question about the legality of VPR's marketing of its ELF-branded electronic cigarettes, including whether in submitting its trademark registration to the USPTO under Class 34 for electronic cigarettes, VPR knew or should have known it was submitting a registration for an unlawful product.

Thus, VPR cannot satisfy the first prong necessary to prove its claims.

## B. VPR Cannot Carry Its Burden to Prove Likelihood of Confusion

Setting aside whether VPR's claims founder on the shores of Defendants' illegality defense, VPR still does not have a substantial likelihood of success on the merits because it has not carried its burden of proving likelihood of confusion. Courts within the Eleventh Circuit examine seven factors in assessing whether consumer confusion is likely: (1) the strength of the asserted mark; (2) the similarity between the asserted mark and the accused mark; (3) the similarity between the goods offered under the two marks; (4) the similarity of the parties' retail outlets or consumers; (5) the similarity of the advertising methods; (6) the alleged infringer's intent to misappropriate the proprietor's goodwill; and (7) actual confusion. *Tana*, 611 F.3d at 774-75. Of these, the type of mark and the evidence of actual confusion are the most important. *Dieter v. B.&H Indus. of S.W. Fla, Inc.*, 880 F.2d 322, 326 (11th Cir. 1989).

VPR's reliance on the USPTO Examining Attorney's citation to its ELF registration in connection with Weiboli's prior application to register ELFBAR is insufficient to support VPR's claim of likely success on the merits on its likelihood of confusion claim. Courts do not recognize *ex parte* trademark examination decisions of USPTO Examining Attorneys as having *res judicata* effect. *See* 5 McCarthy on Trademarks and Unfair Competition § 32.95 (5th Ed. 2022). A district court deciding a trademark infringement claim is not bound by, nor should even be persuaded by, a registration decision rendered by an examining attorney. *Playnation Play Sys. v. Velez Corp.*, 924 F.3d 1159, 1169 (11th Cir. 2019); *see also Royal Palm Properties, LLC v. Pink Palm Properties, LLC*, 950 F.3d 776, 790 n. 9 (11th Cir. 2020) (noting courts not bound by "confusingly similar" analysis).

An analysis of the seven relevant factors suggests that the balance weighs against a finding of likely confusion, and thus also against granting the preliminary injunction.

1. *VPR's ELF Mark is Commercially Weak.*

The strength of the allegedly infringed mark is the second most important factor in the seven-factor balancing test. *Fla. Int'l Univ. Bd. of Trs. v. Fla. Nat'l Univ., Inc.*, 830 F.3d 1242, 1258 (11th Cir. 2016). This factor weighs strongly against a likelihood of confusion, and against entry of a preliminary injunction. Whether a mark is strong or weak is a two-part inquiry that looks to both the mark's conceptual strength and the mark's commercial strength. *Id.* ("It is surely true that focusing solely on conceptual strength is an incomplete method of analysis, since we are also required to examine the marketplace strength of the mark at the time of the litigation.").

"Conceptual strength" evaluates a mark's placement on the generic-to-arbitrary spectrum of marks, while commercial strength measures the marketplace's recognition value of the mark. *See 2 McCarthy on Trademarks and Unfair Competition* § 11:81 (5th Ed. 2021) ("Determining the strength of any mark requires weighing circumstantial evidence of advertising promotion, recognition and any direct evidence of consumer perception, such as by a survey"). VPR relies heavily on where its ELF mark falls on the conceptual strength scale, as a fanciful or suggestive mark, but fails to sufficiently demonstrate its commercial strength.

VPR's sales of ELF-branded electronic cigarettes in the United States have been admittedly "paltry" and since they began in November 2017, have totaled less than \$2.5 million in gross revenue, and only approximately \$1 million in profits. VPR's sales of ELF-branded products began to decline precipitously before Defendants' ELFBAR products gained prominence in the United States, and even before their sales began. Likewise, VPR had minimal sales and revenue as compared to other market participants, such as the Defendants.

While VPR presented evidence that it may have advertised in magazines as well as at point-of-sale, VPR did not submit evidence of any advertising expenditures and acknowledged that ELF products are likely not offered "in a prominent space." With no other evidence of third-party

recognition of its mark, VPR has offered no evidence to suggest it is a “market leader” or that its ELF mark is commercially strong.

Because VPR’s ELF mark lacks commercial strength, this factor weighs against a likelihood of confusion and against entry of a preliminary injunction.

2. *The Marks are Dissimilar in Sight, Sound, Meaning and Overall Commercial Impression.*

Likelihood of confusion is greater when an infringer uses the exact trademark. *See Turner Greenberg Assocs. v. C&C Imps.*, 320 F. Supp. 2d 1217, 1332 (S.D. Fla. 2004). Here, however, the marks are not identical. VPR’s asserted mark is the single-syllable common word ELF. In contrast, the accused mark is ELFBAR, a unitary term comprised of two syllables that creates a different overall impression in terms of sight, sound, meaning, and overall commercial impression. Trademarks are to be considered as a whole, rather than dissected into their component parts. *Lone Star Steakhouse & Saloon, Inc. v. Longhorn Steaks, Inc.*, 106 F.3d 355, 362 (11th Cir. 1997) (holding district court properly assessed the marks as a whole and not just the component words); *see also, e.g., Jack Wolfskin Ausrüstung Fur Draussen GmbH v. New Millennium Sports, S.L.U.*, 797 F.3d 1363, 1372 (Fed. Cir. 2015) (observing that “marks must be viewed ‘in their entirety,’ and it is improper to dissect a mark when engaging in this analysis”); *Juice Generation, Inc. v. GS Enterprises, LLC*, 794 F.3d 1334, 1341 (Fed. Cir. 2015).

VPR erroneously argues for the Court to ignore this requirement and dissect “ELFBAR” because “bar” is commonly used in the e-cigarette industry to refer to bar-shaped e-cigarettes and does not distinguish ELFBAR from ELF. But the law does not allow such division, and regardless, the evidence offered does not support such a view. There is no indication that any person or party refers to ELFBAR as “ELF”; indeed, one witness testified that he had never heard anyone in the

electronic cigarette industry refer to ELFBAR as “ELF,” and the only evidence offered by VPR on the issue does not use “ELF” as a source identifier for sales of products in the United States.

Additionally, VPR’s ELF mark is typically presented with a unique font and enclosed within a circle, whereas Defendants’ ELFBAR mark uses a different font, often running vertically on the device, and frequently is placed in close proximity to a leaf and bubble or circle design on product packaging and advertising.

Properly considered, the differences between VPR’s asserted mark and Defendants’ accused mark “create a visual and phonetic impression that is absent from” VPR’s mark. *Jack Wolfskin*, 797 F.3d at 1371. Thus, this factor favors Defendants.

### 3. *The Parties’ Respective Goods are Dissimilar.*

VPR’s argument that the goods are similar essentially boils down to the notion that the parties’ products fall into the broader category of electronic cigarettes and have a similar shape. However, that is insufficient to show similarity. The similar shapes of the parties’ respective products is inconsequential, as the evidence presented establishes that the shape is widely used in the vaping industry, and VPR does not possess any proprietary rights in that shape. There is nothing unique or distinct about the “bar” shape that would cause a consumer to believe that VPR was the source of Defendants’ ELFBAR products.

Moreover, the goods have different intended uses and capabilities. VPR’s ELF-branded electronic cigarettes are considered “open-system” devices for which a consumer must provide their own liquid solution to vaporize, and which can be used repeatedly. This allows VPR’s ELF-branded products to be used not only with nicotine but with various substances, including oils, vitamins, cannabis, or other products. VPR’s witness testified that the ELF products are intentionally not sold or marketed as nicotine electronic cigarette devices only and are sold empty to allow for other uses.

Alternatively, Defendants' ELFBAR electronic cigarettes are closed-system products considered "disposable," as they contain only nicotine-containing liquids and the consumer throws the device away once the liquids are depleted. Witnesses made clear that within the broader electronic cigarette market, "open system" products like VPR's ELF products are considered distinct from the "disposable" ELFBAR products offered by Defendants. This distinction is underscored by the wide discrepancy in popularity between the subject device types, with disposable products currently vastly more popular than open system products.

The parties' products, once examined beyond a superficial level, are sufficiently dissimilar that this factor weighs in favor of Defendants and against entry of injunctive relief.

4. *The Parties' Respective Customers and Retail Outlets are Dissimilar.*

VPR similarly fails to carry its burden on the fourth likelihood of confusion factor, which is "the similarity of the parties' retail outlets and consumers." *Lone Star Steakhouse*, 122 F.3d at 1382; accord *Seiko Kabushiki Kaisha v. Swiss Watch Int'l, Inc.*, 188 F. Supp. 2d 1350, 1358 (S.D. Fla. 2001) (denying preliminary injunction where "Plaintiff's verified submissions fail to establish a majority of these factors," including similarity of customers and similarity of retail outlets).

VPR explained that most of its sales were wholesale and through a single online retail outlet, its own Honeystick website. However, VPR uses a different distribution network with different master distributors and no Defendant sold through VPR's website.

Similarly, while VPR testified its ELF products are sold in various retail outlets, it offered no testimony or documentary evidence to substantiate those claims other than digital image of an alleged point-of-sale display available for purchase with no evidence that it was ever used in a retail setting or bought by a retailer for use. Indeed, Defendants' witnesses testified that despite extensive experience in the e-cigarette industry and regularly visiting brick-and-mortar retailers and online retail outlets, they had never heard of or encountered VPR's ELF-branded products.

Furthermore, the target customers for the parties' respective products are not the same. As acknowledged by VPR's witness, unlike Defendants' ELFBAR products, VPR does not explicitly market its ELF products to regular nicotine users who want to transition from more harmful combustible cigarettes.

Because the parties' target customers and retail outlets are not the same, this factor also weighs against injunctive relief.

5. *VPR Did Not Demonstrate Use of Similar Advertising Media*

VPR has also not carried its burden to show that the methods of advertising used by the parties for the products at issue are sufficiently similar to support a preliminary injunction.

The only evidence VPR offered on the similarity of advertising is a single trade magazine advertisement from a Business-to-Business magazine, with no indication anyone has ever seen it. VPR provided no evidence of the amount of its advertising expenditures or when that specific advertisement ran in the magazine. Similarly, while VPR's witness testified that the ELF-branded products were advertised at industry trade shows, this was contradicted by Defendants' witnesses' testimony that they had never seen any advertising or marketing for ELF at any trade show.

And, as discussed, while VPR submitted an image of a point-of-sale display that could be bought, there is no indication that it was ever bought or used by any retailer. There also is no evidence that VPR advertised the ELF-branded products online, other than through its own website, or otherwise used the same discrete types of online advertising. *See PlayNation*, 924 F.3d at 1168-69 (finding similarity of advertising since both parties used Google and Amazon keyword advertising, Facebook, and YouTube).

This factor therefore does not support granting a preliminary injunction.

6. *VPR Did Not Establish Improper Intent.*

VPR did not establish that Defendant Weiboli adopted its ELFBAR mark “with the intent of obtaining benefit from the plaintiff’s business reputation.” *See Carnival Corp. v. Seaescape Casino Cruises, Inc.*, 74 F. Supp. 2d 1261, 1268 (S.D. Fla. 1999). Weiboli may have known of VPR’s mark as of July 19, 2021, but this is not sufficient evidence that Weiboli adopted the ELFBAR mark with an intent to trade on VPR’s reputation and goodwill, as prior knowledge alone is insufficient to create an inference of improper intent. *See Fla. Int’l*, 830 F.3d at 1263.

To the contrary, Weiboli has a large portfolio of international trademark registrations and pending applications for its ELFBAR brands, including applications filed before it learned of VPR’s purported U.S. trademark rights. The evidence shows that Weiboli and related companies have registered trademarks or have pending applications for the ELFBAR mark in countries spanning multiple continents, including throughout Europe, Asia, and the Middle East.

Further, witnesses for Defendants Safa Goods and Demand Vape both testified that they had never heard of any electronic cigarette branded as “ELF” before this litigation, despite having years of experience in the electronic cigarette industry. This raises questions not only about any improper intent, but also of the mere existence of any substantial “business reputation” from which Defendants could have benefited.

Without sufficient evidence to show that Defendants adopted the ELFBAR mark with an improper intent, this factor also weighs against preliminary injunctive relief.

7. *VPR Did Not Prove Actual Confusion.*

“Evidence of confusion by actual or potential customers is, of course, the best evidence of a likelihood of confusion.” *Fla. Int’l*, 830 F.3d at 1264. Here, however, VPR has presented no evidence of actual consumer confusion, let alone evidence sufficient to carry its burden.

VPR provided a single, seemingly facetious, text message from a former distributor, but that text does not evidence consumer confusion as it did not impact any sales decision. On the other hand, Defendants testified that they had no indication of customer confusion about the products or their source. Despite selling to thousands of customers, neither defense witness was aware of any instance of confusion between ELFBAR and ELF. Demand Vape’s witness also testified that no customer had ever inquired of Demand Vape or any of its 32 sales representatives about obtaining VPR’s ELF brand.

Even if the text message proffered by VPR could be construed to suggest confusion, a single instance of consumer confusion, even if it does exist, is insufficient to warrant preliminary injunctive relief. *Cf. Fla. Int’l*, 830 F.3d at 1265 (district court reasonably decided that “only a single probative instance of consumer confusion” did not weigh in favor of likelihood of confusion”); *Tana*, 611 F.3d at 779 (finding plaintiff’s purported evidence of actual confusion – one customer’s affidavit – to be “nominal”). Thus, this factor likewise weighs against a preliminary injunction.

In sum, VPR failed to propound evidence showing any of the seven likelihood of confusion factors weigh in its favor, and so falls far short of demonstrating likely success on the merits.

### **III. VPR WILL NOT SUFFER IRREPARABLE HARM ABSENT AN INJUNCTION**

VPR fails to establish that any harm it would suffer is sufficiently “irreparable” to warrant injunctive relief. While the Trademark Modernization Act provides that a rebuttable presumption of irreparable harm applies in the preliminary injunction context upon a finding of likelihood of success on the merits of a claim for trademark infringement, such a presumption does not apply when a party has not made such a showing. *See* 15 U.S.C. § 1116(a); *Proactive Envtl. Prods. Int’l v. Pine Envtl. Servs.*, 2021 U.S. Dist. LEXIS 136302, at \*43, 2021 WL 3025481 (M.D. Fla. May 20, 2021) (finding that the presumption did not apply because the plaintiff failed to show a

substantial likelihood of success on the merits); *UMG Recordings, Inc. v. OpenDeal, Inc.*, 2022 U.S. Dist. LEXIS 117998, at \*25, 2022 WL 2441045 (S.D.N.Y. July 5, 2022) (finding presumption did not apply because of lack of showing of likelihood of success on merits and further finding plaintiff failed to show irreparable harm). As discussed, VPR has failed to make the necessary showing of likelihood on the success on the merits of its claims against Defendants, thus the presumption does not apply. And even if VPR had made such a showing, the evidence submitted by Defendants and before the Court effectively rebut the presumption.

“An injury is ‘irreparable’ only if it cannot be undone through monetary remedies.” *Del Monte Int’l v. GMBH v. Ticofrut SA*, 2017 U.S. Dist. LEXIS 33140, at \*21 (S.D. Fla. Mar. 7, 2017)) (quoting *Ne. Fl. Chapter of Ass’n of Gen. Contractors v. Jacksonville*, 896 F.2d 1283, 12855 (11th Cir. 1990)). Accordingly, “many courts in this district have held monetary damages are sufficient to compensate for lost income.” *Id.*; see also *Excelsior Med. Corp. v. Ivera Med. Corp.*, 2014 U.S. Dist. LEXIS 188632, at \*2 (S.D. Fla. Sept. 29, 2014) (“Lost sales and profits are sufficiently compensated with money damages and, alone, are not considered irreparable harm to justify a preliminary injunction.”).

Courts in this district have also stated that “[t]he mere prospect of harm is not enough” to support granting an injunction. See *Pinnacle Adver. & Mktg. Grp., Inc. v. Pinnacle Adver. & Mktg. Grp., LLC*, 2019 U.S. Dist. LEXIS 144756, at \*4 (S.D. Fla. June 27, 2019). Thus, “the asserted irreparable injury must be neither remote nor speculative, but actual and imminent.” *Id.* at \*4-5; see also *3 Natives Franchising, LLC v. 3 Natives Stuart, LLC*, 2019 U.S. Dist. LEXIS 136631, at \*16 (S.D. Fla. Aug. 13, 2019) (“harm at issue must be actual and imminent, not merely remote or speculative” in rejecting alleged harm that was “conclusory and abstract in nature”).

This can be established with actual evidence of harm—though self-serving allegations are often insufficient. *See, e.g., Ne. Fla. Chapter*, 896 F.2d at 1286 (finding conclusory allegations, even though in verified complaint, inadequate to support injunction); *Invue Sec. Prods.*, 2019 U.S. Dist. LEXIS 167593, at \*13 (M.D. Fla. July 1, 2019) (finding declarations from Plaintiff’s officers, “consist[ing] mainly of conclusory statements [which] lack evidentiary support” insufficient). A sufficiently strong showing of likelihood of confusion may by itself show the potential irreparable injury due to loss of control of reputation, trade, or goodwill, but here no such showing is present, and there is no evidence that VPR has or will suffer any loss of reputation, trade, or goodwill.

VPR has provided no evidence that any loss of sales resulted from Defendants and their use of the ELFBAR mark. And there is a clear temporal disconnect between when ELF-branded products’ sales decreased and when ELFBAR products entered the U.S. market.

After VPR unlawfully introduced its ELF-branded electronic cigarettes in 2017, there was at least a two-year period when the ELF brand could have been established and VPR could have grown its sales and popularity. That is substantially longer than the lifespan of most electronic cigarette products that become successful, and with consumer tastes that change “almost yearly.” Yet VPR’s sales of ELF-branded products were never particularly large and already on the decline well before ELFBAR even entered the U.S. market, with sales slowing in 2020 and continuing to drop through 2021 and 2022.

This decline coincided with the general rise in popularity of closed-system electronic cigarette products and the decline in popularity of open-system electronic cigarette products like VPR’s ELF-branded products. As all witnesses testified, open-system products are less popular and have lower demand because consumers prefer disposable devices like ELFBAR rather than

devices which require consumers to separately purchase nicotine-containing liquid and refill the device before each use. Disposable devices are generally viewed as easier to use and maintain.

With this ongoing and widespread shift in consumer preferences, VPR's prior drop in sales appears to be unrelated to the alleged infringement by Defendants, and also would seem to make it unlikely that more consumers would purchase VPR's ELF-branded products if the Court were to enjoin Defendants from selling the ELFBAR products. Disposable electronic cigarette users are not going to become open-system users overnight (if ever). They would be far more likely to purchase a counterfeit disposable product that passes for ELFBAR.

VPR also has not offered any evidence to support a finding that it will suffer a loss of control of its reputation or goodwill. Such a claim appears to be undermined by the pre-existing and ongoing drop in sales and industry recognition of ELF, reducing its sales and number of customers or potential customers. Any loss of goodwill or relationships with customers appears to result from a larger market-wide shift, and less from anything specifically related to Defendants' use of ELFBAR. Without substantive evidence to support a claim of any such loss, it is too speculative to find that VPR will suffer irreparable injury absent an injunction.

#### **IV. HARM TO THE DEFENDANTS OUTWEIGHS HARM TO VPR**

The balance of harms also strongly disfavors entry of a preliminary injunction, as Defendants will suffer much greater injury than VPR.

As discussed, any decline in sales suffered by VPR are unrelated to any action by Defendants. VPR offered little evidence to support its claim that if Defendants are allowed to continue to sell ELFBAR products, VPR will suffer "both financial harm and nonmonetary harm to its goodwill and reputation." [ECF No. 5 at 16-17]. Such unsupported or self-serving claims are insufficient. *See Nivel Parts & Mfg. Co., LLC v. Textron, Inc.*, 2017 U.S. Dist. LEXIS 65890 (M.D. Fla. May 1, 2017) (finding a conclusory declaration from the plaintiff corporation's president

“does not demonstrate that [plaintiff] has lost market share to [defendant] or quantify [plaintiff’s] expected loss of market share”).

On the other hand, Defendants’ sales of ELFBAR significantly dwarf VPR’s sales of ELF, vastly exceeding in a single year VPR’s total sales over almost five years. As a result, Defendants will suffer significant monetary losses if they are enjoined from selling ELFBAR. Furthermore, both Safa Goods’ and Demand Vape’s principals testified that because they derive a significant portion of their revenues from sales of ELFBAR-branded products, if an injunction is entered and they are forced to stop selling ELFBAR-branded products, they will be forced to lay off a large percentage of their employees. Unlike Defendants, who could recover at least some of their losses against a bond if an injunction is later vacated, those employees will be without a job and unable to recover for their lost earnings.

Additionally, Defendants’ reputation and goodwill with their customers would be harmed by an injunction. These are harms that, as a matter of law, cannot be fully compensated in monetary damages, including by the posting of a bond by VPR pursuant to Federal Rule of Civil Procedure 65(c). *See, e.g., Variable Annuity Life Ins. Co. v. Joiner*, 454 F. Supp. 2d 1297, 1304 (S.D. Ga. 2006) (holding that harm from lost customer accounts, goodwill, and business is irreparable because it is “neither easily calculable, nor easily compensable”). With Defendants unable to sell their most popular product, Defendants’ customers will turn to other distributors, or to counterfeits, to meet their customers’ demand for ELFBAR-branded products.

The balance of harms thus weighs strongly against a preliminary injunction. *See Pandora Jewelers 1995, Inc. v. Pandora Jewelry, LLC*, 703 F. Supp. 2d 1307, 1316 (S.D. Fla. 2010) (holding balance of harms favored defendant that would suffer “significant financial loss, and damage to its reputation and goodwill” if injunction issued).

## V. THE PUBLIC INTEREST DOES NOT FAVOR AN INJUNCTION

The public interest in not being misled as to the origin, source, or sponsorship of trademarked products does not weigh in favor of an injunction where, as here, the likelihood of confusion is minimal or nonexistent. *Ohio Art Co. v. Lewis Galoob Toys, Inc.*, 799 F. Supp. 870, 887 (N.D. Ill. 1992); *Lindebloom v. Plaster City Digital Post, LLC*, No. CV 08-8077, 2009 U.S. Dist. LEXIS 140499, at \*35 (C.D. Cal. Apr. 29, 2009). The public interest also does not favor rewarding parties that eschew federal regulatory requirements—like FDA premarket authorization—with preliminary injunctive relief. And the public interest is not served by the reality that preventing Defendants from selling ELFBAR-branded products will only lead to the market being flooded with counterfeit products that will likely endanger consumers and avoid appropriate federal regulatory oversight.

Defendants’ witnesses testified that when demand for ELFBAR-branded products temporarily outstripped the available supply earlier this year, the market was saturated with counterfeits. These counterfeit items will bear the same markings, logos, and labels as legitimate ELFBAR-branded products, but without the same quality control or assurance of consumer safety. When other popular brands of electronic cigarettes have been removed from the market, or could not satisfy the consumer demand, counterfeits from disreputable manufacturers and distributors took their place, resulting in the public purchasing and using less safe counterfeit products that may contain harmful constituents not present in Defendants’ ELFBAR products.

Even if a more legitimate product were to fill the space left by ELFBAR, that would likely take at least 40 to 90 days, resulting in counterfeits filling the void in the meantime. And, whether a legitimate product could even fill the void is questionable given the previously discussed PMTA requirement for products that enter the market after August 8, 2016.

Contrary to VPR's arguments at the hearing in favor of a low bond, it is unclear how even if only a nominal bond were required, VPR could afford to take aggressive action against the infringing counterfeiters that would emerge. As it stands, VPR does not appear to have acted against any seller of counterfeit ELFBAR-branded products other than the Defendants or other parties that expressly use the ELF mark on other vaping products.

Given the likely consequences of an injunction, the public interest weighs strongly against an injunction.

#### **VI. EVEN IF AN INJUNCTION WERE TO ISSUE, VPR WOULD HAVE TO POST A SUBSTANTIAL BOND**

Notwithstanding the foregoing, if the Court were to grant a preliminary injunction, it must require VPR to post a significant bond as security for Defendants' lost sales and other damages if Defendants are ultimately found to have been wrongfully enjoined. *See* Fed. R. Civ. P. 65(c). "[A]bsent circumstances where there is no risk of monetary loss to the defendant, the failure of a district court to require a successful applicant to post a bond constitutes reversible error." *Hoxworth v. Blinder, Robinson & Co.*, 903 F.2d 186, 210 (3d Cir. 1990).

To determine the appropriate amount of a bond, a court should consider various factors, including: the circumstances of the case, the likelihood of success on the merits of either party, the potential damages and loss for the enjoined party, and hardship imposed upon the applicant. *Glob. NAPs, Inc. v. Verizon New Eng., Inc.*, 489 F.3d 13, 20-21 (1st Cir. 2007). The risk of enjoining a party wrongfully is high and can irrevocably harm the enjoined party without sufficient security, particularly considering the expedited process and limited availability of evidence for hearings on the injunction. *Id.* at 21; *accord Mead Johnson & Co v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000) ("when setting the amount of security, district courts should err on the high side").

Here, the Court must consider the effect of the injunction on each of the eight Defendants and require VPR to post a cash bond that would fairly cover and protect *all* of the Defendants' lost sales, lost revenues, and any subsequent and incidental damages. *Mead Johnson & Co*, 201 F.3d at 888; *Nintendo*, 16 F.3d at 1036. Setting a bond too low, thereby precluding Defendants from recouping all of their damages if the preliminary injunction is reversed or vacated, would constitute an abuse of discretion. *Mead Johnson & Co.*, 201 F.3d at 888.

Sales of ELFBAR-branded products account for a large portion of revenues and profits for at least two of the Defendants, as they testified. As for Safa Goods, about half of its revenue flows from sales of ELFBAR products. Safa Goods and Demand Vape submitted sales records showing nearly \$50 million in gross profits from sales of ELFBAR-branded electronic cigarettes in approximately one year. They also testified that the trajectory of ELFBAR products was still increasing, with ELFBAR-branded products being the most popular electronic cigarettes on the market nationwide.

As discussed, even if another product or products were to ultimately replace ELFBAR if an injunction were granted, it would likely not be Weiboli's product, and the distributor Defendants would still suffer immediate and substantial losses, particularly if their customers sought out counterfeit ELFBAR products from other distributors in an attempt to satisfy the demand from consumers.

Thus, given the evidence of past, current, and expected future sales, the immediate and long-term harm potentially suffered by Defendants, and the number of defendants, if the Court had to set a bond, it would set the bond at \$200 million.

### **CONCLUSION**

For these reasons, the Court DENIES VPR Brands, LP's Motion for Preliminary Injunction.

Dated: December 20, 2022.

Respectfully Submitted,

By: /s/ Tucker C. Motta  
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*Counsel for Defendants*

## CERTIFICATE OF SERVICE

I certify that on December 20, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to the following:

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Boca Raton, FL 33433  
[joel.rothman@sriplaw.com](mailto:joel.rothman@sriplaw.com)  
*Counsel for Plaintiff*

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Tucker C. Motta

# **EXHIBIT H**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
WEST PALM BEACH DIVISION**

VPR BRANDS, LP,

Plaintiff,

V.

Case No. 9:22-cv-81576-AMC

SHENZHEN WEIBOLI TECHNOLOGY  
CO., LTD., et al.

*Defendants.*

## DECLARATION OF MATTHEW GLAUSER

I, Matthew Glauser, pursuant to 28 U.S.C. § 1476, declare under penalty of perjury the following:

1. I am over 18 years of age and would be competent to testify to the information set forth herein if called as a witness in court.
2. I make this declaration based on my own personal knowledge, and review of company records, except where indicated to be on information and belief.
3. I make and submit this declaration in further support of Defendant Ecto World LLC's (also known as Demand Vape) ("Demand Vape") motion to vacate the preliminary injunction in the lawsuit captioned *VPR Brands, LP v. Shenzhen Weiboli Technology Co. Ltd. et al.*, Case No. 9:22-cv-81576 (the "Instant Litigation").
4. I am a co-founder, the president and a partner of Demand Vape.
5. Demand Vape is a New York limited liability company, founded in July, 2013.

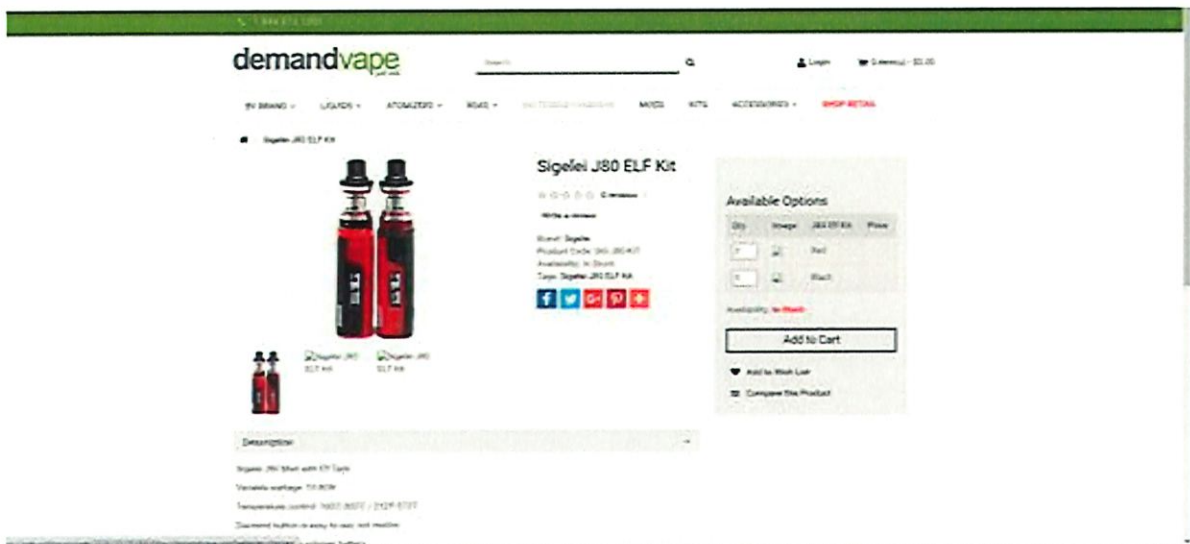
6. In nearly a decade since its founding, Demand Vape has grown to become one of the largest, if not the largest, distributor of electronic cigarettes in the United States.
7. Demand Vape sells its electronic cigarette products in forty-nine (49) states to approximately five thousand (5,000) retail customers.
8. In my capacity as co-founder and president of Demand Vape, I am familiar with Demand Vape's operations, including but not limited to, its purchase and sales of third-party branded products.
9. Demand Vape first met GD Sigelei Electronic Tech Co. Ltd. ("GD Sigelei") at a trade show in the United States in early 2014.
10. Demand Vape met with GD Sigelei at its factory in China in late 2014.
11. Soon thereafter, we began to purchase SIGELEI branded products for sale in the United States.
12. Over the next few years, and no later than the beginning of 2016, we were considered by GD Sigelei to be a "Super VIP Customer", which is equivalent to what we consider to be a "master distributor."
13. As a Super VIP Customer and/or master distributor, we were, and still are, entitled to certain preferential treatment, including heavily discounted pricing, early access to newly released products, custom designed and manufactured products (OEM), and specialized packaging.
14. As a Super VIP Customer and/or master distributor, Demand Vape's relationship with GD Sigelei has been, and currently remains, akin to a partnership in that Demand Vape has helped GD Sigelei design products, packaging, and the like, by

providing its input, and has played a critical role in launching, developing, and fostering the growth and success of GD Sigelei's brands and products.

15. Since the start of Demand Vape's relationship with GD Sigelei in 2014, I personally have visited GD Sigelei at its factory in China at least thirty (30) times.
16. GD Sigelei also shares with us product samples, product images, and marketing and promotional materials to allow us to promote its SIGELEI branded products to our extensive customer base.
17. Beginning in 2016, Demand Vape, through its sister company, Magellan Technology Inc. (the purchasing arm of Demand Vape), purchased ELF branded electronic cigarette, and accessories ("ELF Products") from GD Sigelei.
18. In an April, 2016 email advertisement sent to us by GD Sigelei, the tank ELF Product was described as follows:



19. In 2016, Demand Vape purchased \$13,850 of ELF Products.
20. Demand Vape has made sales of ELF Products in each year from 2016 through 2023, except 2018.
21. Demand Vape has continuously held inventory of ELF Products from 2016-2023.
22. Demand Vape has continuously offered for sale ELF Products from 2016-2023 to sub-distributors, retailers and direct to consumers through our company sales team and through our website (<https://demandvape.com/ipv-v3-mini-elf-ada-replacement-2pk-coil-cartridges-1?search=ipv%20elf>).
23. For example, below is a true and correct screenshot from on or about November 2016 of the Elf Products on Demand Vape's website:



24. I testified in the Instant Action with regard to my knowledge of “elf” branded products. At that time, I did not recall that Demand Vape purchased and sold the ELF Products in light of the sheer size of Demand Vape's business.
25. While I am intimately familiar with the SIGELEI brand, which our company has had a direct influence in establishing through our nearly ten (10) year partnership

with GD Siglelei as a master distributor, I did not specifically recall GD Siglelei's ELF Products.

26. Demand Vape has an inventory of more than thirty thousand (30,000) SKUs of electronic cigarette products so it is reasonable for me not to know all sub-brands we have offered for sale, particularly since I do not take part in the day-to-day purchase decisions for Demand Vape.
27. On or about late February 2023, Demand Vape engaged Epstein Drangel LLP to represent it in the Instant Action, and in light of a lawsuit brought by Plaintiff against GD Siglelei, my attorneys became aware of GD Siglelei's ELF Products, and asked me about them.
28. In response to Epstein Drangel LLP's inquiries, Demand Vape conducted a thorough review of its prior records, and uncovered its purchases, sales, and promotions of the ELF Products from 2016 through the present.
29. A summary of Demand Vape's relevant U.S. sales figures for GD Siglelei's ELF Products through 2023, which are based on Demand Vape's sales records that I have reviewed, which are kept in the ordinary course of Demand Vape's business,<sup>1</sup> appears below:

Product	2016	2017	2018	2019	2020	2021	2022	2023
Elf Coil	\$2,436.61	\$344.54	\$-	\$-	\$-	\$-	\$-	\$-
Elf Tank	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-
J150/J80 Kit w/ Elf Tank	\$14,945.00	\$-	\$-	\$-	\$-	\$-	\$-	\$-
IPV ELF ADA Coil	\$-	\$-	\$-	\$93,444.11	\$9,970.11	\$12,522.03	\$3,156.27	\$324.43
<b>Total:</b>	\$17,381.61	\$344.54		\$93,444.11	\$49,970.11	\$12,522.03	\$3,156.27	\$324.43

<sup>1</sup> Demand Vape's underlying sales records can be produced to the Court upon its request.

Executed this 16<sup>th</sup> day of March, 2023.

A handwritten signature in black ink, appearing to read "Matthew Glauser", written over a horizontal line.

Matthew Glauser

# **EXHIBIT I**

**DECLARATION OF MATTHEW JONATHAN GLAUSER**

I, Matthew Jonathan Glauser, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury as follows:

1. I am over 18 years of age and would be competent to testify as to the information set forth herein if called as a witness in court.

2. I make this declaration based on my own personal knowledge.

3. I am the Chief Strategy Officer of Ecto World LLC.

4. Ecto World LLC is a wholesale distributor of vapor products, including, until the district court's recent entry of a preliminary injunction, ELFBAR products.

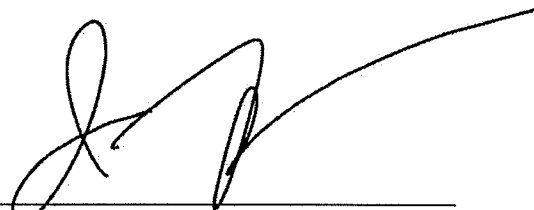
5. As of February 2023, ELFBAR accounted for 40 % of Ecto World's total revenue, and a substantial portion of Ecto World's profits.

6. After the preliminary injunction took effect, in March 2023, Ecto World's total revenue was approximately 18.38% less than average revenue for the months of January and February 2023.

7. There are 326 customers that had previously purchased ELFBAR products on multiple occasions that have not made any further purchases of any vapor products from Ecto World since entry of the preliminary injunction on February 23, 2023.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 12th day of April 2023.

  
Matthew Jonathan Glauser

# **EXHIBIT J**

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS  
Tyler Division

MAGELLAN TECHNOLOGY, INC.;	)	
2225 Kenmore Avenue, Suite 110	)	
Buffalo, New York 14207,	)	
	)	
and	)	
	)	
VAPOR TRAIN 2 LLC;	)	
3500 McCann Road	)	
Longview, Texas 75605,	)	
	)	
Plaintiffs,	)	
	)	Case No.
v.	)	
	)	
U.S. FOOD AND DRUG ADMINISTRATION;	)	
ROBERT M. CALIFF, M.D., Commissioner for	)	
Food and Drugs;	)	
10903 New Hampshire Avenue	)	
Silver Spring, Maryland 20903,	)	
	)	
U.S. DEPARTMENT OF HEALTH AND	)	
HUMAN SERVICES;	)	
XAVIER BECERRA, Secretary of Health and	)	
Human Services;	)	
200 Independence Avenue, S.W.	)	
Washington, D.C. 20201,	)	
	)	
Defendants.	)	

**VERIFIED COMPLAINT**  
**(TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**  
**REQUESTED)**

Plaintiffs Magellan Technology, Inc. (“Magellan”) and Vapor Train 2 LLC (“Vapor Train”), for their Verified Complaint against the United States Food and Drug Administration, Robert M. Califf, M.D., Commissioner for Food and Drugs (collectively, “FDA”), the United States Department of Health and Human Services, and Xavier Becerra, Secretary of the Department of Health and Human Services (collectively, “HHS”), hereby state as follows:

## NATURE OF THE ACTION

1. Through this action, Plaintiffs seek a declaratory judgment that FDA has violated the Administrative Procedure Act by issuing a Refuse to Accept (“RTA”) order for twelve bundled Premarket Tobacco Product Applications (“PMTAs”) that Magellan submitted for various electronic nicotine delivery system products it markets.

2. Plaintiffs contend that FDA acted arbitrarily, capriciously, and otherwise not in accordance with applicable law in issuing the RTA order because the agency (i) invoked regulations governing PMTA acceptance that do not apply to Magellan’s PMTA and (ii) failed to consider timely amendments containing required content that Magellan properly submitted but which FDA failed to link to the corresponding applications because of its own failure to issue Submission Tracking Numbers (“STNs”) to Magellan for the underlying applications.

3. Plaintiffs seek (i) a temporary restraining order and preliminary injunction staying the RTA order pending the outcome of this action; and (ii) a final judgment setting aside the RTA order and remanding to FDA for further review of Magellan's PMTAs.

## THE PARTIES

4. Plaintiff Magellan Technology, Inc., is a corporation headquartered in Buffalo, New York. Magellan distributes ENDS products nationwide, including in this district. Magellan is the master distributor of all Hyde- and JUNO-branded ENDS products. Through its scientific advisors, on May 12 and 13, 2022, Magellan submitted twelve bundled applications for marketing authorization for a range of Hyde- and JUNO-branded ENDS products to FDA.

5. Plaintiff Vapor Train 2 LLC is a Texas limited liability company headquartered and with two retail stores in Longview, Texas. Until FDA issued the RTA order, Vapor Train

purchased Hyde-branded ENDS products from Magellan and sold them to consumers at retail through its two stores.

6. Defendant United States Food and Drug Administration is a division of Defendant Department of Health and Human Services (“HHS”). The headquarters and principal place of business of FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland 20903. The headquarters and principal place of business of HHS is 200 Independence Avenue, S.W., Washington, D.C. 20201. Defendant Robert M. Califf, M.D., is the Commissioner of the Food and Drug Administration and is sued in his official capacity. Defendant Xavier Becerra is the Secretary of Health and Human Services and is sued in his official capacity.

### **JURISDICTION AND VENUE**

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331. This Court has the authority to grant the declaratory relief requested by Plaintiffs pursuant to 28 U.S.C. §§ 2201 and 2202. The Court also has the authority to hold unlawful and set aside FDA’s actions pursuant to 5 U.S.C. §§ 702 and 706 and to grant temporary and preliminary injunctive relief pursuant to 5 U.S.C. § 705.

8. This Court has personal jurisdiction over Defendants FDA, HHS, Commissioner Califf, and Secretary Becerra in their official capacities, as each is an agency or official of the United States Government.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) as the district wherein Plaintiff Vapor Train 2 LLC resides.

## FACTS

### **A. ENDS Products are “Tobacco Products” under the Tobacco Control Act**

10. Electronic nicotine delivery system (“ENDS”) products are regulated by FDA as “tobacco products” under the Tobacco Control Act (“TCA”), 21 U.S.C. §§ 387, *et seq.*, because they “contain[] nicotine from any source” and are “intended for human consumption.” 21 U.S.C. § 321(rr)(1). As such, they are subject to the requirements of Subchapter IX of the Federal Food, Drug and Cosmetic Act (“FDCA”).

11. Section 910 of the FDCA, 21 U.S.C. § 387j, requires that any tobacco product that was not commercially marketed as of February 15, 2007, receive a marketing order from FDA prior to being commercially marketed in the United States.

12. Prior to April 15, 2022, ENDS products containing nicotine that was synthetically manufactured or otherwise not derived from tobacco plants did not qualify as “tobacco products” and were not subject to Section 910’s premarket authorization requirements because the statutory definition of a “tobacco product” extended only to products “made or derived from tobacco that [are] intended for human consumption, including any component, part, or accessory of a tobacco product.” 21 U.S.C. § 321(rr) (2009). However, the Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, §111(a) expanded the statutory definition to include products containing nicotine “from any source” effective April 15, 2022.

13. As a result, manufacturers and distributors of ENDS products were required to submit premarket tobacco applications for these synthetic nicotine products. If they submitted PMTAs by May 14, 2022, they would not be in violation of the Section 910’s marketing authorization requirement during the 60-day period up through July 13, 2022. *See id.* at § 111(d).

**B. FDA has Historically Extended Enforcement Discretion to ENDS Products with Timely Submitted and Pending PMTAs**

14. May 14, 2022, was not the first time that manufacturers and distributors of ENDS products were required to submit PMTAs for their products in order to keep them on store shelves.

15. When the Tobacco Control Act was first enacted in 2009, its requirements originally applied only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. § 387a(b). The TCA’s requirements would only apply to other products meeting the statutory definition of a “tobacco product” if FDA “by regulation deems” such products to be “tobacco products.” *Id.*

16. Through its so-called “Deeming Rule,” 81 Fed. Reg. 28974 (May 10, 2016) (codified at 21 C.F.R. § 1143.1), FDA deemed ENDS products containing nicotine derived from tobacco plants to be tobacco products.

17. However, because thousands, if not millions, of ENDS products were already commercially marketed in the United States, in the Deeming Rule’s preamble, FDA introduced a discretionary enforcement policy that allowed for delayed compliance periods for ENDS products. *See* 81 Fed. Reg. at 29009-15.

18. Under this discretionary enforcement policy, PMTA submissions were originally required to be filed in 24 months, or by August 8, 2018. 81 Fed. Reg. at 28977-78, 29011. Tobacco products, including ENDS products, already on the U.S. market would not be subject to FDA enforcement action in the meantime or while a timely submitted PMTA was pending FDA review. *Id.*

19. FDA’s deadline for the filing of PMTAs under its discretionary enforcement policy, however, changed multiple times over the succeeding years, and these changes resulted in

significant litigation. *See Vapor Technology Ass’n v. FDA*, 977 F.3d 496, 497-502 (6th Cir. 2020) (summarizing history of litigation surrounding PMTA submission deadline).

20. Ultimately, to comply with an order from the United States District Court for the District of Maryland,<sup>1</sup> FDA specified that ENDS products for which a PMTA was submitted by September 9, 2020, could continue to be commercially marketed for a period of up to one year after September 9, 2020, provided that the PMTA remained pending and FDA had taken no adverse action on the application.<sup>2</sup>

21. Even after September 9, 2021, however, FDA has continued to exercise enforcement discretion to allow the continued marketing of ENDS products containing tobacco-derived nicotine for which timely submitted PMTAs are still pending or, in certain cases, where FDA originally issued a marketing denial order on the PMTA, but then either administratively stayed or retracted the marketing denial order. *See, e.g., Turning Point Brands, Inc. v. FDA*, No. 21-3855, ECF No. 19, p. 9-10 (6th Cir. Oct. 8, 2021); *My Vape Order, Inc. v. FDA*, No. 21-71302, ECF No. 45, p. 2 (9th Cir. Dec. 30, 2021); *Juul Labs, Inc. v. FDA*, No. 22-1123, Doc. # 1953737 (D.C. Cir. July 6, 2022).

22. With respect to ENDS products containing non-tobacco-derived nicotine, prior to July 13, 2022, FDA publicly indicated that it would utilize the same approach, with ENDS products that are the subject of pending applications “subject to enforcement at FDA’s discretion.” *See* Nicholas Florko, Stat News, *FDA appears to hold off on crackdown on synthetic nicotine products, despite calls from Congress* (July 8, 2022).

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<sup>1</sup> *See* April 22, 2020 Order in *American Academy of Pediatrics v. FDA*, No. 8:18-cv-00883-PWG (D. Md.).

<sup>2</sup> U.S. Food & Drug Admin., Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised), at 27-28 (Apr. 2020), <https://www.fda.gov/media/133880/download>.

23. To date, to the knowledge of Petitioners, FDA has not issued a Warning Letter to any manufacturer or importer of an ENDS product regarding a product for which a timely filed PMTA remains pending.

**C. Regulations and Forms Governing FDA’s Premarket Tobacco Product Application Requirements**

24. In June 2019, FDA issued its final guidance on PMTAs for ENDS products. FDA, Guidance for Industry, *Premarket Tobacco Applications for Electronic Nicotine Delivery Systems* (June 2019), <https://bit.ly/2XZIEah>.

25. In September 2019, FDA issued a proposed rule governing PMTAs. Premarket Tobacco Product Applications and Recordkeeping Requirements, Proposed Rule, <https://bit.ly/2m5c2g8>.

26. FDA published its final PMTA Rule setting out the requirements for a PMTA and the procedures for FDA’s review of such applications in the *Federal Register* on October 4, 2022. Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed. Reg. 55300 (Oct. 4, 2020), <https://bit.ly/3Dt3d57>.

27. In March 2020, FDA included in the reopening of the comment period on the proposed PMTA rule the potential for adding a new Form 4057b to the PMTA submission requirements. *See* 85 Fed. Reg. 13840, 13840-41 (Mar. 10, 2020).

28. The purpose of the form was for submitting PMTAs that contained multiple ENDS products in a single “bundled” submission. *Id.* at 13841.

29. The Office of Management and Budget (“OMB”) granted its approval to FDA’s inclusion of the amended Form 4057b in its PMTA forms. Office of Management and Budget, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, ICR 202003-0910-008; <https://bit.ly/3f9qcsv>.

30. On April 13, 2022, two days before the expanded definition of “tobacco products” established by the Consolidated Appropriations Act, 2022, took effect, FDA sought emergency authority from OMB to amend Form 4057b, and on April 14, 2022, OMB granted emergency authorization for FDA to use the amended Form 4057b. Office of Management and Budget, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, ICR 202204-0910-012; <https://bit.ly/3sv5YMY>.

31. FDA did not publish the amended Form 4057b on its website where potential applicants could access it until April 28, 2022. FDA, *Premarket Tobacco Product Applications*, <https://bit.ly/3Dapi7h>.

32. FDA failed to publish notice of the amendment in the Federal Register until May 16, 2022, two days *after* the PMTA submission deadline for the newly defined “tobacco products.” 87 Fed. Reg. 29749 (May 16, 2022).

33. FDA’s regulations require that applicants submit their PMTAs electronically. *See* 21 C.F.R. § 1114.49(a). This may be done either through FDA’s Center for Tobacco Products electronic submission portal, or “CTP Portal,” or FDA’s separate agency-wide “Electronic Submissions Gateway,” although FDA’s website recommends submitting PMTAs through the CTP Portal due to better functionality.<sup>3</sup>

#### **D. Magellan’s PMTAs**

34. On May 12 and 13, 2022, Magellan, through its scientific advisors, timely submitted eleven separate bundled PMTAs for Juno and Hyde-branded ENDS products containing non-tobacco-derived nicotine.

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<sup>3</sup> *See* <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>.



supplemental amendment to identify the original application to which the amendment was to be linked.

44. Despite FDA's CTP Portal failing to provide STNs for Magellan's PMTAs, SKYTE provided identifying information for each of the amendments so FDA could link them to the prior submissions.

45. Like the initial bundled applications themselves, each supplemental amendment submitted on August 18, 2022, identified in the zipped file name itself the particular ENDS device to which the amendment related.

46. The amendments submitted by SKYTE on August 18, 2022, contained a completed Form 4057a, as well as a Form 4057 and a Form 4057b for each of the bundled submissions. The "Submission Summary" section on page 7 of 14 of these Forms 4057a stated that the purpose of the supplemental submissions was to supply Forms 4057 and 4057b for each bundled submission.

47. As part of its PMTAs, Magellan submitted a substantial number of dual language documents provided by the manufacturer of the subject ENDS products that include content in both English and Mandarin Chinese.

48. These dual language documents include documents related to the manufacturer's processes for manufacturing and maintaining quality control over the subject ENDS products, including specifications, protocols, and standard operating procedures.

49. These dual language documents did not result from the translation of original Mandarin Chinese-language documents into English. Rather, they are original dual language documents that are kept and maintained in the ordinary course of business by the manufacturer as a dual language document, not as a document that is only in Mandarin Chinese.

50. The manufacturer maintains these design and production documents in both languages in the normal course of its business specifically because they are for an American customer, Magellan, and the manufacturer knows that they will be required for FDA's review. Indeed, the manufacturer maintains many similar dual language documents for its own branded ENDS products for which it has sought premarket authorization from FDA.

**E. FDA's Refuse to Accept Order**

51. On October 6, 2022, FDA issued a Refuse to Accept order to Magellan for its ENDS products in the bundled PMTAs assigned STNs: PM0005337; PM0005370; PM0005438; PM0005442; PM0005480; PM0005508; PM0005514; PM0005521; PM0006321; PM0006322; and PM0005595. A copy of the RTA order with confidential manufacturer information redacted is attached hereto as **Exhibit A**.

52. The RTA order was the first notice Magellan received from FDA regarding any purported deficiency in any of its bundled PMTAs.

53. For each of the PMTAs submitted by SKYTE, FDA determined that the submissions failed to include FDA Form 4057b–Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 C.F.R. § 1105.10(a)(6) and 21 C.F.R. § 1114.7(b).

54. FDA also found the SKYTE submissions deficient for failing to include a certification statement signed by an authorized representative as required by 21 C.F.R. § 1114.7(a)(11) and 21 C.F.R. § 1114.7(m).

55. The certification statement, however, was found in the Forms 4057 that Skyte uploaded through the CTP Portal as part of the amendments on August 18, 2022.

56. The RTA order noted that “although you submitted additional submissions which may have been intended to amend your applications,” the submissions “did not specify the STNs assigned to the original submission within FDA form 4057a” in violation of 21 C.F.R. § 1114.9.

57. The RTA order states that “although your submission(s) may include the required content for a PMTA, they lack these necessary elements to accurately identify the purpose of the submission as well as the applications, products, and content which is being amended.”

58. A review of Appendix B to the RTA order, listing amendments and additional submissions received by FDA for Magellan, suggests that FDA erroneously found nine of SKYTE’s supplemental submissions from August 18, 2022, to be lacking Form 4057a-Premarket Tobacco Product Application Amendment and General Correspondence Submission.

59. The RTA order also states that the bundled PMTAs assigned STNs PM0005337 and PM0005595 contained portions that were not in English and “[w]hile they contain[ed] the original language version alongside an English translation of those portions, they do not include a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation certification statement as required by 21 C.F.R. 1114.7(b)(1).”

60. The RTA order itself states in bold that Magellan “cannot introduce or deliver for introduction” any of the ENDS products subject to the RTA order “into interstate commerce in the United States” and that doing so would be a violation of the FDCA and could result in enforcement action by FDA.

61. Penalties for selling unauthorized ENDS products can include both substantial civil penalties and criminal prosecution. 21 U.S.C. §§ 331, 333.

62. Simply resubmitting the bundled PMTAs would not provide an adequate remedy for Magellan because, to Magellan’s understanding, FDA will not consider exercising enforcement discretion as to any non-tobacco-derived nicotine ENDS products unless the corresponding PMTAs were submitted by May 14, 2022, and remain pending.

#### **F. The MDO Threatens Magellan and Vapor Train’s Businesses**

63. As a result of the RTA order, Vapor Train has stopped selling Magellan’s Hyde-branded ENDS products and does not plan to purchase more of the products for so long as the RTA order remains in effect.

64. Vapor Train has a number of customers that regularly purchase the Hyde products subject to the RTA order from it, as well as other products, and expects that it may lose those customers’ business as a result of the RTA order.

65. At the time the RTA order issued, Magellan had sold the Hyde and Juno products at issue to over 4,500 retailers nationwide.

66. Magellan had already spent over \$1 million on the PMTAs at the time the RTA order issued and plans to spend over \$10 million on the PMTAs in total.

67. Magellan’s Hyde and Juno products subject to the RTA order compete with numerous other ENDS products that either have received marketing authorization from FDA or, while they also lack marketing authorization from FDA, are not subject to FDA enforcement because the PMTAs submitted by the manufacturers of those products are still pending or, if FDA has issued a marketing denial order on the application, the agency has administratively stayed or retracted the marketing denial order and is re-reviewing the application.

68. The RTA order means that Magellan thus stands to lose substantial sales to the manufacturers and distributors of these products in the highly competitive ENDS industry.

69. Even if the RTA order is stayed at a later date, because other ENDS manufacturers and distributors have not received RTA orders or other adverse actions and FDA continues to exercise enforcement discretion as to their products, Magellan will lose market share to them, as well as associated customer goodwill.

### **COUNT I**

#### **(Declaratory Judgment that Defendants Violated the Administrative Procedure Act)**

70. Plaintiffs incorporate herein by reference the allegations set forth in paragraphs 1 through 69, above.

71. As a federal agency, FDA is subject to the requirements of the Administrative Procedure Act, including the prohibition against agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2).

72. FDA’s RTA order is a “final agency action” for which there is no other adequate remedy in a court. *See* 5 U.S.C. § 704. On November 1, 2022, the United States Court of Appeals for the Fifth Circuit held that RTA orders are not directly reviewable by it under Section 912 of the FDCA, 21 U.S.C. § 387*l*. *See* Nov. 1, 2022 Order in *Boomtown Vapor, LLC v. FDA*, Case No. 22-60467 (5th Cir. 2022).

73. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law in issuing the RTA order to Magellan.

74. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that Magellan’s applications assigned STNs PM0005337 and PM0005595 lacked translation certification statements as required by 21 C.F.R. § 1114.7(b)(1) when such translation certification statements were unnecessary because the documents at issue were original dual language documents that were already in English and so were not “[d]ocuments

that have been translated from another language into English” as specified in 21 C.F.R. § 1114.7(b)(1).

75. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that Magellan’s applications assigned STNs PM0005337; PM0005370; PM0005438; PM0005442; PM0005480; PM0005508; PM0005514; PM0005521; PM0006321; and PM0006322 failed to include FDA Form 4057b—Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 C.F.R. § 1105.10(a)(6) and 21 C.F.R. § 1114.7(b) because Magellan, through its scientific advisor, submitted timely amendments that contained FDA Form 4057b for each such application prior to the issuance of the RTA order.

76. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that Magellan’s applications assigned STNs PM0005370; PM0005438; PM0005442; PM0005480; PM0005508; PM0005514; PM0005521; PM0006321; and PM0006322 failed to include a certification statement signed by an authorized representative as required by 21 C.F.R. § 1114.7(a)(11) and 21 C.F.R. § 1114.7(m) because the certification statements were found in the Forms 4057 that were submitted as timely amendments on August 18, 2022, before FDA issued the RTA order dated October 6, 2022.

77. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by failing to consider Magellan’s timely amendments submitted on August 18, 2022, on the grounds that the amendments did not include or reference the Submission Tracking Numbers assigned to the original bundled applications to which the amendments related when FDA itself failed to assign the original bundled applications corresponding Submission Tracking Numbers. FDA similarly acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the basis that Magellan’s amendments dated August 18, 2022, did not specify the STNs

assigned to the corresponding original submission within the Forms 4057a in violation 21 C.F.R. § 1114.9 and that the amendments “lack the necessary elements to accurately identify the purpose of the submission as well as the applications, products, and contents which is being amended.”

78. An actionable controversy of a justiciable nature exists between Plaintiffs and Defendants regarding whether FDA’s aforementioned conduct constitutes a violation of the Administrative Procedure Act.

79. As a direct and immediate result of FDA’s actions in violation of the requirements of the Administrative Procedure Act, Magellan and Vapor Train are suffering ongoing and irreparable harm in that the RTA order prohibits Plaintiffs from introducing or delivering Magellan’s subject ENDS products into interstate commerce. If the RTA order were stayed or vacated, Vapor Train and Magellan could return to the *status quo ante* of continuing to market the ENDS products under an exercise of FDA’s enforcement discretion while the PMTAs remained under FDA review. *See Wages & White Lion Investments, LLC v. FDA*, 16 F.4th 1130, 1143-44 (5th Cir. 2021).

WHEREFORE, Plaintiffs Magellan Technology, Inc. and Vapor Train 2 LLC request a temporary, preliminary, and permanent injunction and a declaratory judgment:

- A. Declaring that FDA acted arbitrarily, capriciously, and not in accordance with law in issuing the RTA order to Magellan;
- B. Temporarily and preliminarily staying the RTA order for the duration of this action;
- C. Setting aside FDA’s RTA order and remanding the issue back to FDA for further review of Magellan’s PMTA in accordance with law;
- D. Awarding Plaintiffs’ their reasonable attorneys’ fees, costs, and expenses under 28 U.S.C. § 2412 and other applicable authority; and

E. Granting such other and further relief as is necessary and appropriate.

Respectfully submitted,

Dated: November 3, 2022

By: /s/ G. Blake Thompson

**G. Blake Thompson**

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*Counsel for Plaintiffs Magellan Technology, Inc.  
and Vapor Train 2 LLC*

**VERIFICATION**

I verify under penalty of perjury that the facts set forth in the foregoing complaint, other than those facts relating to Vapor Train 2 LLC, which Omar Dawud is separately verifying, are true and correct to the best of my information, knowledge, and belief.

A handwritten signature in black ink, appearing to read 'J. Glauser', is written over a horizontal line.

Mr. John Glauser  
Chief Strategy Officer  
Magellan Technology, Inc.

VERIFICATION

I verify under penalty of perjury that the facts set forth in the foregoing complaint relating to Vapor Train 2 LLC are true and correct to the best of my information, knowledge, and belief.



Omar Dawud  
Member  
Vapor Train 2 LLC

**EXHIBIT A**



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

October 06, 2022

**REFUSE TO ACCEPT**

Magellan Technology Inc.  
Attention: Vincent Angelico, Ph.D, Chief Scientific Officer & Co-founder  
Accorto Regulatory Solutions  
4551 Macon Farms Drive  
Powhatan, VA 23139

**FDA Submission Tracking Numbers (STNs):** Multiple STNs, see Appendix A

Dear Vincent Angelico:

We are refusing to accept your PMTAs<sup>1</sup> for the tobacco products identified in Appendix A. Note that attributes in Appendix A may display converted values. Refer to Appendix B for a list of amendments and additional submissions received.

Your applications do not meet the regulatory requirements to permit substantive review for the following reasons:

1. PM0005337.PD1-PD20, PM0005370.PD1-PD18, PM0005438.PD1-PD18, PM0005442.PD1-PD18, PM0005480.PD1-PD18, PM0005508.PD1-PD18, PM0005514.PD1-PD18, PM0005521.PD1-PD18, PM0006321.PD1-PD10, and PM0006322.PD1-PD18 were not submitted using the required FDA form, FDA Form 4057b – Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 CFR 1105.10(a)(6) and 21 CFR 1114.7(b). See 21 CFR 1114.27(a)(1)(i) (providing that FDA may refuse to accept an application that does not comply with 21 CFR 1114.7(b)).

The following information is required in FDA Form 4057b for a closed e-cigarette:

- a. Product name, including brand and sub-brand
- b. Product category
- c. Product subcategory
- d. Package type
- e. Product quantity
- f. Characterizing flavor
- g. Additional properties needed to uniquely identify the tobacco product (e.g., nicotine source (i.e., tobacco derived, non-tobacco derived, both, or none))
- h. Length
- i. Diameter
- j. Wattage
- k. Battery capacity
- l. E-liquid volume
- m. Nicotine concentration
- n. PG/VG ratio

<sup>1</sup>Premarket Tobacco Product Application (PMTA) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Without the required FDA form, your applications are administratively incomplete. The absence of these required FDA forms impedes FDA ingestion and processing of applications.

2. Portions of PM0005337.PD1-PD20, PM0005595.PD1-PD104, and PM0005595.PD209 are not in English. While they contain the original language version alongside an English translation of those portions, they do not include a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation certification statement as required per 21 CFR 1114.7(b)(1). *See* 21 CFR 1114.27(a)(1)(i) (providing that FDA may refuse to accept an application that does not comply with 21 CFR 1114.7(b)). This information will help FDA ensure that the English language translations of documents are complete and accurately reflect the content of the original documents.
3. PM0005370.PD1-PD18, PM0005438.PD1-PD18, PM0005442.PD1-PD18, PM0005480.PD1-PD18, PM0005508.PD1-PD18, PM0005514.PD1-PD18, PM0005521.PD1-PD18, PM0006321.PD1-PD10, and PM0006322.PD1-PD18 do not include a certification statement that is signed by an authorized representative as required by 21 CFR 1114.7(a)(11), and 21 CFR 1114.7(m). A signed certification authenticates that the information and accompanying submission are true and correct, that no material fact has been omitted, that the signer is authorized to submit the information on the applicant's behalf, and that the signer understands that, under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties. Without this certification, FDA cannot confirm the PMTAs are complete, accurate, and ready for review. In future applications, we recommend you use the appropriate certification statement for your application from FDA Form 4057 and have it signed by your designated authorized representative.

Additionally, although you submitted additional submissions which may have been intended to amend your applications, one submission was not submitted using FDA Form 4057a – Premarket Tobacco Product Application Amendment and General Correspondence Submission and did not contain the certification statement. The remaining submissions did not specify the STNs assigned to the original submission within FDA Form 4057a. 21 CFR 1114.9 explains that “[a]n amendment must include the appropriate form and specify the STN assigned to the original submission and, if submitted other than at FDA’s request, the reason for submitting the amendment. An amendment must also include the certification statement set forth in § 1114.7(m), with the appropriate information inserted, and signed by an authorized representative of the applicant.” Thus, although your submission(s) may include the required content for a PMTA, they lack these necessary elements to accurately identify the purpose of the submission as well as the applications, products, and content which is being amended. The absence of this information impedes FDA processing and does not contain enough information to know if the data can be trusted (e.g., if the individual submitting the information is authorized to amend a certain product or application). The required FDA form allows FDA to process your submission(s). The required certification statement authenticates that the information and accompanying submission are true and correct, that no material fact has been omitted, that the signer is authorized to submit the information on the applicant’s behalf, and that the signer understands that, under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties. Without this required information, your submission(s), which may be intended to amend your application(s), will not be considered in FDA’s review.

**You cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.**

If you choose to submit new PMTAs for these products, you must fulfill all requirements set forth in section 910(b)(1) and 21 CFR Part 1114. In order to do so, you may cross-reference a Tobacco Product Master File submission. Your new PMTAs should include all information necessary to support acceptance and filing so FDA may perform a substantive scientific review.

Refer to Appendix C for additional information to consider submitting in future submissions. The information provided in this letter may not represent a complete list of comments and potential deficiencies.

If you have any questions, please contact Kenna Randall, M.P.H., Regulatory Health Project Manager, at (301) 796-4164 or Kenna.Randall@fda.hhs.gov.

Sincerely,

Digitally signed by Benjamin Apelberg -  
S

Date: 2022.10.06 07:55:20 -04'00'

Benjamin Apelberg, Ph.D.  
Deputy Director  
Office of Science  
Center for Tobacco Products

**Enclosures:**

- Appendix A – New Tobacco Products Subject of This Letter
- Appendix B – Amendments and Additional Submissions Received for This Applicant
- Appendix C -- Additional Comments That May Be Considered for Future Submissions